

# EXHIBIT 2-C

[Group 1 Deficient  
Complaints]

**IN THE UNITED STATES DISTRICT COURT**  
**MIDDLE DISTRICT OF TENNESSEE**

WILLIAM LAPISKA

Plaintiff,

v.

AMERIDOSE, LLC, MEDICAL SALES  
MANAGEMENT, INC., MEDICAL SALES  
MANAGEMENT SW, INC., GDC  
PROPERTIES MANAGEMENT, LLC, ARL  
BIO PHARMA, INC. D/B/A ANALYTICAL  
RESEARCH LABORATORIES, BARRY J.  
CADDEN, GREGORY CONIGLIARO, LISA  
CONIGLIARO CADDEN, DOUGLAS  
CONIGLIARO, CARLA CONIGLIARO,  
GLENN A. CHIN, and SPECIALTY  
SURGERY CENTER, PLLC d/b/a  
SPECIALTY SURGERY CENTER,

Defendants.

Civil Action No. \_\_\_\_\_

**JURY DEMAND**

**COMPLAINT**

The Plaintiff, William Lapiska, for his cause of action against the Defendants respectfully states unto the Court as follows:

**INTRODUCTION**

1. This lawsuit arises as a result of a widespread outbreak of fungal meningitis over the past year that has affected people in at least 20 states and caused over 60 deaths. Over 700 people have been diagnosed with meningitis.

2. The United States Food and Drug Administration ("FDA") and the Centers for Disease Control ("CDC") have identified fungus present in several separate lots of preservative-free injectable steroids, specifically, methylprednisolone acetate (sometimes referred to as

“MPA”), that was compounded and distributed by New England Compounding Pharmacy, Inc. d/b/a New England Compounding Center (“NECC”) as the cause of the fungal meningitis outbreak and the resulting injuries and deaths.

3. Many thousands of vials of steroids compounded at NECC have been recalled but this recall was too late for Plaintiff William Lapiska, and for many others, who have suffered serious and at times catastrophic injuries.

4. Upon information and belief, between June 2012 and September 2012, Specialty Surgery Center, PLLC d/b/a Specialty Surgery Center (“Specialty Surgery”) purchased hundreds or thousands of vials of MPA from NECC and then sold and administered the MPA to patients including Mr. Lapiska.

5. On, or about, July 18, 2012 and September 18, 2012, Mr. Lapiska received epidural steroid injections (“ESI”) at Specialty Surgery. During these procedures, Mr. Lapiska was injected with MPA.

6. Mr. Lapiska’s July 18, 2012 injection and/or his September 18, 2012 injection came from one or more contaminated lots of MPA that were purchased from NECC, which were subsequently recalled by NECC.

7. Mr. Lapiska’s July 18, 2012 injection and/or September 18, 2012 injection of MPA caused him personal injury.

### **PARTIES**

8. William Lapiska is a citizen and resident of the State of Tennessee, residing at 248 Lakewood Drive, Fairfield Glade, Cumberland County, Tennessee 38558.

9. Defendant Ameridose, LLC (“Ameridose”) is a Massachusetts limited liability company organized and domesticated under the laws of the Commonwealth of Massachusetts with a principal place of business at 205 Flanders Road, Westborough, Massachusetts 01581.

The managers of Ameridose are Gregory Conigliaro and Barry Cadden. Ameridose's registered agent is Gregory Conigliaro.

10. Defendant Medical Sales Management, Inc. ("MSM") is a Massachusetts corporation organized and domesticated under the laws of the Commonwealth of Massachusetts with its principal place of business at 697 Waverly Street, Framingham, Massachusetts 01702. Douglas Conigliaro is the President and a Director of MSM. Barry Cadden is the Treasurer and a Director of MSM. Gregory Conigliaro is the Secretary and a Director of MSM. MSM's registered agent is Gregory Conigliaro.

11. Defendant Medical Sales Management SW, Inc. ("MSMSW") is a Massachusetts corporation organized and domesticated under the laws of the Commonwealth of Massachusetts with its principal place of business at 697 Waverly Street, Framingham, Massachusetts 01702. Douglas Conigliaro is the President and a Director, Barry Cadden is the Treasurer and a Director, Gregory Conigliaro is the Secretary and a Director and Lisa Conigliaro. MSMSW's registered agent is Gregory Conigliaro.

12. Defendant GDC Properties Management, LLC ("GDC"), is a Massachusetts limited liability company organized and domesticated under the laws of the Commonwealth of Massachusetts with its principal place of business at 701 Waverly Street, Framingham, Massachusetts 01702. GDC's manager and registered agent is Gregory Conigliaro.

13. Defendant ARL Bio Pharma, Inc. d/b/a Analytical Research Laboratories ("ARL") is an Oklahoma corporation organized and domesticated under the laws of the State of Oklahoma with a principal place of business at 840 Research Parkway, Suite 546, Oklahoma City, Oklahoma 73104. Thomas C. Kupiec is the Chief Executive Officer and registered agent of ARL.



14. Defendant Barry J. Cadden (“Barry Cadden”) is an individual residing at 13 Manchester Drive, Wrentham, Massachusetts 02093 and a citizen and resident of the Commonwealth of Massachusetts. Barry Cadden is the President of NECC, which is a Massachusetts corporation. At least until October 2012, Barry Cadden was NECC’s licensed Pharmacist Manager of Record. Barry Cadden is a founder and Manager of Ameridose and was involved in Ameridose’s day to day operations. Barry Cadden is the Treasurer and a Director of MSM and MSMSW.

15. Defendant Gregory Conigliaro (“Gregory Conigliaro”) is an individual residing at 1 Mountain View Drive, Framingham, Massachusetts 01701 and a citizen and resident of the Commonwealth of Massachusetts. Gregory Conigliaro is a principal owner and the general manager of NECC, as well as NECC’s Treasurer, Secretary, Vice President, registered agent, and one of its Directors. Gregory Conigliaro provided financial advice, oversaw day to day operations, and regularly appeared in the NECC facility. Gregory Conigliaro is the founder and a Manager of Ameridose and involved in Ameridose’s day to day operations. Gregory Conigliaro is Secretary and a Director of MSM and MSMSW.

16. Defendant Lisa Conigliaro Cadden (“Lisa Cadden”) is an individual residing at 13 Manchester Drive, Wrentham, Massachusetts 02093 and a citizen and resident of the Commonwealth of Massachusetts. Lisa Cadden is a board member, Director and, at least until October 2012, a pharmacist at NECC. Lisa Cadden, upon information and belief, compounded drugs and was involved in the day to day operations of NECC.

17. Defendant Douglas Conigliaro (“Douglas Conigliaro”) is an individual residing at 15 Hale Drive, Dedham, Massachusetts 02026 and a citizen and resident of the Commonwealth of Massachusetts. Douglas Conigliaro is the President and a Director of MSM and MSMSW.

Douglas Conigliaro, upon information and belief, is involved in the day to day operations of NECC, Ameridose, MSM, and MSMSW.

18. Defendant Carla Conigliaro (“Carla Conigliaro”) is an individual residing at 15 Hale Drive, Dedham, Massachusetts 02026, and a citizen and resident of the Commonwealth of Massachusetts and is a Director of NECC.

19. Defendant Glenn A. Chin (“Glenn Chin”) is an individual residing at 173 Mechanic Street, Canton, Massachusetts 02021 and a citizen and resident of the Commonwealth of Massachusetts. At least until October 2012, Glenn Chin was a pharmacist at NECC. Glenn Chin, upon information and belief, compounded drugs at NECC.

20. Defendant Specialty Surgery Center, PLLC d/b/a Specialty Surgery Center (“Specialty Surgery”) is an active for profit limited liability Company organized and domesticated under the laws of the State of Tennessee. Specialty Surgery’s principal place of business is located at 116 Brown Avenue, Crossville, TN 38555-7703. Specialty Surgery’s registered agent for service of process is Donathan M. Ivey, Brown Avenue, Crossville, TN 38555-7703. At all times while providing and selling drug products to Mr. Lapiska at Specialty Surgery, the physicians, nurses, staff, and other personnel were agents, apparent agents, employees or representatives of Specialty Surgery and were acting within the course and scope of their employment, agency, or apparent agency with Specialty Surgery. Accordingly, Specialty Surgery, under the doctrine of *respondeat superior*, is vicariously liable for any negligent acts and omissions of their employees, agents, or representatives committed in the course and scope of their employment or agency while providing and selling drug products to Mr. Lapiska.

21. The individuals and entities described in paragraphs 9-19 are sometimes collectively referred to as the “NECC Related Defendants.”

**JURISDICTION AND VENUE**

22. This Court has subject matter jurisdiction over the parties pursuant to 28 U.S.C. § 1331 because this action arises under the laws or treaties of the United States. Specifically this Court has jurisdiction pursuant to 28 U.S.C. § 1334(b) because as described herein this case is related to a case under title 11.

23. On December 21, 2012, NECC filed a petition for Bankruptcy protection under Chapter 11 of the Bankruptcy Code: New England Compounding Pharmacy, Inc., Debtor, United States Bankruptcy Court for the District of Massachusetts, Case no. 12:19882-HJB. A United States Trustee was subsequently appointed to administer the Bankruptcy Estate. The Bankruptcy Court has not yet established a deadline for the filing of claims against NECC's bankruptcy estate In re New England Compounding Pharmacy, Inc.

24. According to NECC's Bankruptcy Trustee, NECC has express contractual indemnification obligations including but not limited to Barry Cadden, Gregory Conigliaro, Lisa Cadden, Carla Conigliaro, Glenn Chin, GDC and MSM. Some if not all of the aforementioned individuals are insureds under NECC's insurance policies. Adversarial cases seeking recovery of damages for the benefit of the bankruptcy estate and its unsecured creditors have been filed in NECC's bankruptcy against each of the NECC Related Defendants.

25. This case is related to the NECC Bankruptcy because the outcome of the proceeding certainly could have some effect on the bankruptcy estate.

26. Lawsuits alleging death or injury based on contaminated MPA have been filed around the country. On February 12, 2013, the Judicial Panel on Multidistrict Litigation (MDL No. 2419) issued an order under 28 U.S.C. § 1407 transferring various federal-court proceedings to the United States District Court for the District of Massachusetts for coordinated or consolidated pretrial proceedings. The transferred actions are pending in the United States

District Court for the District of Massachusetts in the Multidistrict Litigation action styled: IN RE: New England Compounding Pharmacy, Inc. Products Liability Litigation, United States District Court, District of Massachusetts, MDL No. 1:13-md-2419-FDS. The transferred cases have been assigned to the Honorable F. Dennis Saylor, United States District Judge, for pre-trial proceedings and coordination.

27. Upon information and belief, Specialty Surgery presently intends to seek, and will seek, relief from the stay in order to pursue contribution or indemnity claims against NECC for all or some portion of the damages sought by this Complaint. In addition or in the alternative, Specialty Surgery presently intends to file, and will file, claims in NECC's bankruptcy proceeding seeking indemnification or contribution for all or some portion of the damages sought by this Complaint.

28. By Order dated May 31, 2013, Judge Saylor, ruled that the New England Compounding Pharmacy, Inc. Multi District Litigation Court has subject-matter jurisdiction over any cases pending in federal court or state court against entities or individuals "affiliated" with NECC whether or not NECC is named as a defendant. Those NECC affiliated entities and individuals referred to by Judge Saylor in his May 31, 2013 Order include the defendants described in paragraphs 9-19.

29. In addition, or in the alternative, this Court has subject-matter jurisdiction over all claims against Specialty Surgery pursuant to 28 U.S.C. § 1367 in that all claims are so related to claims in this action within the original jurisdiction of this Court that they form part of the same case or controversy under Article III of the United States Constitution.

30. Venue is proper and appropriate in the United States District Court for the Middle District of Tennessee pursuant to 28 U.S.C. § 1391(b)(2) in that all or a substantial part of the

events and actions giving rise to the matters asserted in the Complaint occurred in Cumberland County, Tennessee.

31. At all times relevant the Defendants were engaged in the business of developing, compounding, marketing, distributing, promoting, selecting, purchasing and/or selling or administering either directly, or indirectly steroids in the State of Tennessee from which they derived significant and regular income.

32. Defendants are subject to the jurisdiction of this Court in that they are generally present in Tennessee, have transacted business within the State of Tennessee, and acting individually and/or through their agents and employees have committed tortious actions and omissions in Cumberland County, Tennessee that have proximately caused the injuries that are the subject of this lawsuit.

33. The NECC related Defendants are further subject to the jurisdiction of this Court as a result of contracting to supply goods and things in Tennessee, by conducting or soliciting business in Tennessee, by engaging in a persistent course of conduct in Tennessee, and by deriving substantial revenue from goods used or consumed or services rendered in Tennessee.

#### **STATEMENT OF FACTS**

34. NECC is an entity that has filed for bankruptcy and is protected by the automatic stay provisions of 11 U.S.C. § 362. Prior to NECC filing for bankruptcy, numerous plaintiffs filed suit against NECC in Tennessee and other states, all of which were eventually removed and transferred to the United States District Court for the District of Massachusetts in the Multidistrict Litigation action styled: IN RE: New England Compounding Pharmacy, Inc. Products Liability Litigation, United States District Court, District of Massachusetts, MDL No. 1:13-md-2419-FDS.

35. NECC was a compounding pharmacy that compounded, distributed and/or sold drugs to purchasers throughout the United States, including Tennessee.

36. Upon information and belief, NECC was a privately-held company that was owned and controlled by Barry Cadden, Gregory Conigliaro, Douglas Conigliaro, Carla Conigliaro and Lisa Cadden.

37. Ameridose, GDC, MSM and MSMSW were affiliates of NECC at all relevant times.

38. At least until October 2012, Gregory Conigliaro was involved in co-managing day-to-day operations of NECC, MSM, MSMSW, Ameridose and GDC.

39. At least until October 2012, Lisa Cadden was a licensed pharmacist who, upon information and belief, compounded medications including MPA at NECC.

40. At least until October 2012, Glenn Chin was a licensed pharmacist who, upon information and belief, compounded medications including MPA at NECC.

41. At least until October 2012, Barry Cadden was a licensed pharmacist. In addition to being NECC's President, Barry Cadden was NECC's licensed Pharmacist Manager of Record. Upon information and belief, Barry Cadden compounded medications including MPA at NECC.

42. "Manager of Record or Pharmacist Manager of Record," as defined by 247 CMR 2.00, "means a pharmacist, currently registered by the [Massachusetts] Board [of Registration in Pharmacy] pursuant to 247 CMR 6.07, who is responsible for the operation of a pharmacy or pharmacy department in conformance with all laws and regulations pertinent to the practice of pharmacy and the distribution of drugs."

43. Ameridose, according to an application signed by Gregory Conigliaro and filed with the Massachusetts Board of Registration in Pharmacy on May 14, 2012, is a "distribution

center to entities of common ownership – currently Ameridose and NECC, as well as other Properly Licensed Facilities in the future.”

44. On information and belief, upon the direction of NECC’s principals, on April 11, 2011, Ameridose employee Michelle Rivers requested certification for pharmacy technicians employed by NECC for use in an inspection of NECC’s facilities by the Massachusetts Board of Registration in Pharmacy.

45. On or about August 24, 2012, Ameridose posted an employment opportunity for Registered Pharmacists to work for NECC in Framingham, Massachusetts. In the posting, potential applicants were told to contact [mlord@medicalesalesmgmt.com](mailto:mlord@medicalesalesmgmt.com). Upon information and belief, there were many other occasions where employees of Ameridose, MSM and/or MSMSW would perform services for NECC at the direction of NECC’s principals.

46. Between 2006 and the present, Ameridose and NECC would often share a booth at conferences and conventions with a single banner listing both company names. During that same time, Ameridose and NECC would hold an annual Christmas party for employees of both companies.

47. MSM and/or MSMSW printed materials for and marketed both NECC’s and Ameridose’s products, including MPA. One former employee of MSM and/or MSMSW has stated: “I didn’t think there was any difference [between Ameridose and NECC].”

48. Through September 2012, both NECC and Ameridose used MSM and/or MSMSW for sales and marketing functions. NECC’s privacy policy on its website referred to the “Ameridose Privacy Policy.” In 2012, NECC salespersons recommended NECC’s “sister company,” Ameridose, for drug compounds that NECC did not have available.



49. MSM and/or MSMSW shared office space owned by GDC Properties with NECC in Framingham, Massachusetts.

50. Since it was formed as a limited liability company in 2006, Ameridose has been controlled by NECC.

51. Both Ameridose and NECC were controlled by Conigliaro and Cadden family members.

**Claims against the NECC Related Defendants**

52. NECC has a well-known history of adverse events relating to its operation as a compounding pharmacy. According to the Majority Memorandum for the November 14, 2012 Oversight and Investigations Subcommittee Hearing, NECC has been the subject of multiple complaints to and investigations by the FDA and the Massachusetts Board of Registration in Pharmacy (“MBP”) over the past decade often focusing on unsterile conditions at NECC’s facilities. For example, the FDA issued a Warning Letter to NECC in 2006. The FDA letter details numerous problems at NECC including the sale of compounded drugs without patient-specific prescriptions, compounding copies of commercially available drugs, selling misbranded compounded drugs, and problems with storage and sterility. That warning letter has been available to the public on the FDA’s website for years.

53. Between January 2012 and August 2012, NECC’s environmental monitoring program for its compounding facility yielded numerous microbiological isolates (bacteria and mold) within the Clean Room used for the production of methylprednisolone acetate. NECC, Barry Cadden, Gregory Conigliaro, Lisa Cadden, Douglas Conigliaro, Carla Conigliaro, Glenn Chin, Ameridose, MSM and/or MSMSW and GDC knew or should have known of these findings. NECC, Barry Cadden, Gregory Conigliaro, Lisa Cadden, Douglas Conigliaro, Carla Conigliaro, Glenn Chin, Ameridose, MSM and/or MSMSW and GDC failed to investigate those



isolates and made no effort to identify those isolates. NECC, Barry Cadden, Gregory Conigliaro, Lisa Cadden, Douglas Conigliaro, Carla Conigliaro, Glenn Chin, Ameridose, MSM and/or MSMSW and GDC failed to perform any product assessments for the products made in the Clean Room where the isolates were found. NECC, Barry Cadden, Gregory Conigliaro, Lisa Cadden, Douglas Conigliaro, Carla Conigliaro, Glenn Chin, Ameridose, MSM and/or MSMSW and GDC failed to take any corrective actions with regards to the isolates that were found. Despite these findings, NECC continued to compound MPA, and Ameridose, MSM and/or MSMSW continued to distribute marketing materials to customers and potential customers touting the cleanliness of the NECC laboratories.

54. On September 26, 2012 in the wake of dozens of cases of fungal meningitis associated with NECC's injectable steroid MPA, state agents raided NECC's lab in a strip mall on Waverly Street in Framingham, Massachusetts.

55. NECC's few remaining employees were scrubbing the compounding areas with bleach. Despite this last-ditch effort, the "clean" rooms were filthy. A leaky boiler stood in a pool of stagnant, dirty water. The autoclaves used to sterilize the product were discolored, tarnished, and contained visible moisture. The air intake came from vents located about 100 feet from a mattress recycling facility that released copious amounts of dust and other contaminants into the air. The air vents in the "clean" rooms were covered with dirt and white fuzz. The metal shelf in the "clean" room used to prepare MPA was covered in a reddish-brown, cloudy substance.

56. Investigators determined that NECC's internal records showed dozens of instances of bacterial and fungal contamination within the NECC facility over at least the past

nine months. NECC ignored these test results. NECC never even attempted to get rid of these microbial contaminants.

57. Eighty-three out of three-hundred twenty one observed vials from one of three recalled lots of MPA contained a greenish-black substance visible to the human eye. Seventeen other vials contained a white filamentous material. All fifty out of fifty vials tested confirmed the presence of live microbes (whether fungal or bacterial). The CDC and FDA later confirmed the presence of fungus in unopened vials of NECC's MPA. This is the same fungus that the CDC confirmed was present in at least forty fungal meningitis cases.

58. Inspections of NECC's sister company Ameridose revealed similarly deplorable conditions, including countless instances of visible contamination of the hoods and rooms used to prepare drug products, insect infestations, birds flying through areas where purportedly sterile products were packaged and stored, and tubs being used to collect rain water that poured through the chronically leaky roof above the "clean" rooms. Ameridose, like NECC, persistently ignored and failed to investigate at least fifty-three instances of known microbiological contamination. Ameridose also hid adverse events associated with its products, failing to report them to the FDA as required by law and instead classifying these events as "patient responses" or "non-complaints" and taking no action to address them.

59. The CDC determined that three lots of 80 mg/ml MPA produced by NECC between May 21 and September 26, 2012 were contaminated with potentially deadly pathogens.

60. In late September 2012, NECC recalled the following lots of MPA (PF) 80 mg/ml that it had compounded and sold: MPA (PF) 80 mg/ml Injection, Lot #05212012@68, BUD 11/17/2012; MPA (PF) 80 mg/ml Injection, Lot #06292012@26, BUD 12/26/2012; and MPA (PF) 80 mg/ml Injection, Lot #08102012@51, BUD 2/6/2013.

61. NECC identified Specialty Surgery as one of the healthcare providers that received vials of MPA that were part of the September 2012 recall.

62. On or about October 3, 2012, the Massachusetts Department of Public Health (“DPH”) secured the surrender of NECC’s license to operate as a compounding pharmacy.

63. On October 6, 2012, NECC announced that it was recalling “all products currently in circulation that were compounded at and distributed from its facility in Framingham, Massachusetts.”

64. On or about October 8, 2012, at the request of DPH, Barry Cadden and Glenn Chin “voluntarily” ceased their practice as pharmacists. Lisa Cadden also has “voluntarily” ceased her practice as a pharmacist. Upon information and belief, none of them have practiced as a pharmacist since “voluntarily” ceasing their practice.

65. On or about October 22, 2012, the Massachusetts Board of Registration in Pharmacy authorized DPH to request the “voluntary” permanent surrender of the licenses of Barry Cadden, Glenn Chin, Lisa Cadden and NECC. According to DPH, “[i]f the three pharmacists and NECC do not comply, the Board authorized staff to proceed with permanent revocation.”

66. One of the Massachusetts regulations promulgated by the Massachusetts Board of Registration in Pharmacy pertinent to NECC’s operation as a compounding pharmacy mandated that “[t]he premises of the pharmacy or pharmacy department shall at all times be kept in a clean and sanitary manner.” 247 CMR 6.02(1).

67. Over the last ten years, ARL has conducted sterility testing on samples of MPA compounded by NECC, including samples from Lot #05212012@68, BUD 11/17/2012; Lot #06292012@26, BUD 12/26/2012; and Lot #08102012@51, BUD 2/6/2013.

68. From May through August 2012, NECC sent several samples of its MPA to ARL for sterility testing. As one example, on or about May 21, 2012, NECC sent to ARL two 5ml vials of MPA from a batch of 6,528 vials that came from Lot 05212012@68, which had been compounded by NECC on May 21, 2012.

69. On May 22, 2012, ARL received and tested the two 5ml vials of MPA that NECC sent to ARL on or about May 21, 2012. ARL sent to NECC a Microbiology Report dated May 25, 2012, which stated that the two vials had been tested on May 22, 2012 and that the “preliminary” results from the sterility test using test method USP 71 showed that the two 5ml vials of MPA that NECC sent to ARL on or about May 21, 2012, were “sterile.” ARL’s report to NECC further noted that the preliminary results were observed “after approximately 72 hours of incubation.”

70. Pursuant to the protocols of test method USP 71, sterility testing on a batch of more than 6,000 vials of MPA should have been conducted on at least 20 vials from the batch.

71. On or about August 10, 2012, NECC caused one 5ml vial of MPA to be sent to ARL for sterility testing from a batch of several thousand vials that are from Lot #08102012@51, BUD 2/6/2013.

72. The Microbiology Reports issued by ARL to NECC between May and September 2012 concerning the sterility testing of MPA indicated that the sterility tests performed by ARL were conducted in compliance with USP 71.

73. During the summer of 2012, MSM and/or MSMSW sales representatives, on behalf of NECC and Ameridose, distributed copies of the May 25, 2012, ARL Microbiology Report concerning the testing of the vials of MPA from Lot 05212012@68 to customers and/or

potential customers in a packet of marketing materials intended to highlight the safety and sterility of the MPA compounded by NECC.

74. ARL was aware of the risks posed by compounding pharmacies, specifically including the risks posed by NECC's compounding practices.

75. In 2002, ARL found that four samples of a steroid compounded by NECC were contaminated with potentially deadly endotoxins.

76. ARL allowed compounding pharmacies such as NECC to submit an inadequate number of samples for sterility testing, which practice did not comply with USP 71 requirements.

77. GDC which is an acronym for "Gregory D. Conigliaro" owns the real property and is responsible for maintenance and structural improvements at 685-705 Waverly Street, Framingham, Massachusetts.

78. From 1998 until at least October 2012, GDC leased a portion of the premises at Waverly Street to NECC, MSM and MSMSW.

79. In an on-line posting for a property management position at GDC, which appeared on or before October 25, 2012, GDC stated that it "owns an 88,000 square foot facility on seven acres in downtown Framingham. GDC currently has eight major tenants." GDC described one of the duties and responsibilities of the GDC property manager as follows: "Insure all tenants operate their businesses in accordance with facility, local [and] state . . . rules and regulations."

80. GDC maintained a high degree of control over the premises leased by NECC.

81. Until October 2012, NECC, Ameridose, ARL, Barry Cadden, Lisa Cadden, and Glenn Chin compounded, tested, marketed and/or distributed MPA.

82. GDC and Gregory Conigliaro knew that NECC was compounding preservative-free MPA at 697 Waverly Street, and further knew that this medication was injected into humans and was required to be sterile.

### **NECC and Risks of Pharmacy Compounding**

83. The serious risks of pharmacy compounding were also the subject of considerable public discussion in the pharmacy community and the medical community before the subject fungal meningitis outbreak. The risks associated with compounded drugs have been known for years.

84. In 2002, the CDC published a report regarding at least two cases of fungal meningitis arising from contaminated medication used in epidural injections. The report concluded that “purchasers of pharmaceuticals should determine if supplies are provided from a compounding pharmacy that...follows appropriate measures to ensure that injectable products are free of contamination.”

85. On March 24, 2005, *USA Today* published a front page article with the following headline: “**Safety concerns grow over pharmacy-mixed drugs**”. That article discussed growing concern over the fact that drugs produced in bulk by compounding pharmacies are not FDA approved and are not subject to the same oversight as drugs produced by pharmaceutical companies.

86. In 2006, the FDA conducted a survey of compounded drug products. They collected thirty-six samples from compounding pharmacies across the United States during unannounced visits. Twelve of the 36 samples (33%) failed analytical testing. The FDA survey concluded “poor quality compounded drugs are a serious public health concern, as improperly compounded products have been linked to grave adverse events, including deaths.”

87. In May 2007, the FDA published an article titled “The Special Risks of Pharmacy Compounding.” That article highlighted numerous adverse events involving compounded products. It also warned of the emergence of large scale compounding operations that were clearly operating outside the bounds of traditional compounding practice.

88. In 2010, the FDA posted an educational video on YouTube regarding concerns over the quality of compounded drugs.

89. On November 5, 2010, the American Society of Anesthesiologists, the American Society of Health-System Pharmacists (“ASHP”) and other medical societies published a joint report regarding drug shortages. That report included an article written by the ASHP stating as follows:

Compounding pharmacies have also pursued the production of drugs that are in short supply. Caution is warranted because preparations from these pharmacies may not meet applicable state or federal standards (e.g., United States Pharmacopeia chapter 797 or FDA labeling requirements). The sources of raw materials used by compounding pharmacies have been questioned, and apparent lapses in quality control have resulted in serious patient injury, including death. Compounding pharmacies may also present patient risks; several deaths have been associated with improperly sterilized compounded products.

90. In May 2012, the CDC published a report regarding fungal infections arising from medications obtained from a compounding pharmacy. That report advised that “contamination of compounded sterile preparations has caused outbreaks. Since 1990, FDA has learned of approximately 200 adverse events associated with 71 compounded products.”

#### **Fungal Meningitis Outbreak**

91. In September 2012, health officials identified an outbreak of fungal meningitis which investigators traced back to the MPA compounded by NECC.

92. According to the CDC, fungal meningitis occurs when the protective membranes covering the brain and spinal cord are infected with a fungus. Fungal meningitis is rare and



usually caused by the spread of a fungus through blood to the spinal cord. Fungal meningitis is not transmitted from person to person.

93. According to the CDC, symptoms of meningitis include the following: new or worsening headache; fever; sensitivity to light; stiff neck; new weakness or numbness in any part of the body; slurred speech; and increased pain, redness or swelling at the injection site. Death may result from meningitis.

94. According to the CDC, symptoms of fungal meningitis are similar to symptoms of other forms of meningitis; however, they often appear more gradually and can be very mild at first. In addition to typical meningitis symptoms, like headache, fever, nausea, and stiffness of the neck, people with fungal meningitis may also experience confusion, dizziness, and discomfort from bright lights. Patients might just have one or two of these symptoms.

**Mr. Lapiska is injected with MPA from NECC and Suffers Personal Injury**

95. On July 18, 2012 and September 18, 2012, Mr. Lapiska was injected by Dr. Kenneth Lister (“Dr. Lister”) at the Specialty Surgery Center with MPA.

96. Mr. Lapiska’s July 18 and/or September 18, 2012 injections came from one or more contaminated lots of MPA purchased from NECC. The contaminated lots were subsequently recalled by NECC.

97. Mr. Lapiska’s July 18 and/or September 18, 2012 injections of MPA caused him personal injury.

98. By letter dated October 6, 2012, Mr. Lapiska was notified by Specialty Surgery that the MPA used in three (3) clinics across the State of Tennessee “may not have been sterile.”

99. Mr. Lapiska did not discover, and reasonably could not have discovered, until after October 6, 2012 that he had received contaminated MPA.



100. Mr. Lapiska was seen by Dr. Kenneth Lister on October 12, 2012, due to the recurrence of his back pain symptoms, and was thereafter referred by Dr. Lister to Dr. Mark Pierce, an infectious disease specialist, in Cookeville, Tennessee for evaluation of a possible fungal infection due to the administration of potentially contaminated MPA.

101. Mr. Lapiska underwent multiple spinal taps and MRIs and was eventually diagnosed with a fungal inter-spinal abscess, which required him to be hospitalized in Cookeville Regional Medical Center for approximately four days.

102. On October 25, 2012, Specialty Surgery sent Mr. Lapiska a letter because he had received “an epidural injection ... between July 18<sup>th</sup>, 2012 and September 18, 2012” wherein he was administered MPA produced by NECC which was “implicated in the multistate outbreak of fungal meningitis and joint infections.”

103. Ms. Lapiska has suffered and continues to suffer harm, injury, and damages as a result of his exposure to one or more of the three recalled contaminated lots of MPA.

### **CAUSES OF ACTION**

#### **COUNT I - NEGLIGENCE (Against NECC Related Defendants)**

104. As the designer, tester, compounder, seller, marketer and/or distributor of consumer products, the NECC related Defendants owed a duty to Mr. Lapiska to comply with existing standards of care, and to exercise due care, in providing a safe and quality product to Mr. Lapiska.

105. Specifically, but without limitation:

- a. Ameridose, MSM/MSMSW, GDC, Barry Cadden, Gregory Conigliaro, Lisa Cadden, Douglas Conigliaro, Carla Conigliaro and Glenn Chin owed Mr. Lapiska a duty to provide MPA that was safe and free of contamination.

- b. ARL owed Mr. Lapiska a duty to properly conduct tests to insure that the MPA was safe and free of contamination.
- c. NECC Related Defendants sold MPA in bulk to Specialty Surgery, but they were not authorized to compound and sell MPA in bulk, instead they were only allowed to fill individual prescriptions for individual patients written by appropriately licensed health care providers.

106. Defendants breached those duties, and were otherwise negligent in their design, compounding, sale, testing, marketing and distribution of the recalled steroid medication, which was administered to Mr. Lapiska. The Defendants failed to exercise due care in accordance with the standard of care and skill required of, and ordinarily exercised by, a designer, compounder, tester, seller, marketer and distributor of steroid medications, as licensed to do so by the Commonwealth of Massachusetts. The Defendants, by and through their supervisors, staff and agents engaged in designing, compounding, storing, testing, selling, marketing and distributing MPA in a negligent manner.

107. Defendants further breached those duties by failing to properly design, compound, test and distribute MPA so that it would not be contaminated with fungus; by failing to properly maintain its facilities where it compounded its medications in a clean, sanitary manner; by failing to oversee the security and quality control of its compounding and distribution facilities; by allowing contaminated and unsafe compounded medications to reach the stream of commerce for use by Mr. Lapiska; and by failing to hold the components of the recalled MPA.

108. Ameridose, MSM/MSMSW, GDC, ARL, Barry Cadden, Gregory Conigliaro, Lisa Cadden, Douglas Conigliaro, Carla Conigliaro and Glenn Chin breached the duties owed to Mr. Lapiska by failing to use reasonable care in designing, compounding, testing, marketing, distributing and/or selling MPA.

109. The negligence of Ameridose, MSM/MSMSW, GDC, ARL, Barry Cadden, Gregory Conigliaro, Lisa Cadden, Douglas Conigliaro, Carla Conigliaro and Glenn Chin was a proximate cause of Mr. Lapiska's injuries and damages.

**COUNT II - NEGLIGENCE PER SE**

(Against all NECC Related Defendants except ARL)

110. Ameridose, MSM/MSMSW, GDC, Barry Cadden, Gregory Conigliaro, Lisa Cadden, Douglas Conigliaro, Carla Conigliaro and Glenn Chin owed Mr. Lapiska a duty to maintain the premises of the pharmacy "in a clean and sanitary manner[.]" 247 CMR 6.02(1), and free from contamination.

111. Ameridose, MSM/MSMSW, GDC, Barry Cadden, Gregory Conigliaro, Lisa Cadden, Douglas Conigliaro, Carla Conigliaro and Glenn Chin breached the duties owed to Mr. Lapiska by failing to use reasonable care in maintaining the premises of the pharmacy "in a clean and sanitary manner[.]" 247 CMR 6.02(1), and free from contamination.

112. Defendants also violated Massachusetts' laws and its pharmacy licensing obligations.

113. The aforementioned actions by Ameridose, MSM/MSMSW, GDC, Barry Cadden, Gregory Conigliaro, Lisa Cadden, Douglas Conigliaro, Carla Conigliaro and Glenn Chin were a proximate cause of Mr. Lapiska's injuries and damages.

**COUNT III - NEGLIGENT SUPERVISION**

(Against NECC Related Defendants)

114. Defendants Ameridose, MSM/MSMSW, GDC, ARL, Barry Cadden, Gregory Conigliaro, Lisa Cadden, Douglas Conigliaro, Carla Conigliaro and Glenn Chin had an obligation and duty to exercise due care, and comply with the then existing standard of care, to investigate and hire professional and competent employees to create, test, package, market and distribute the compounded medications and to maintain the facility and its premises, and to make

sure the compounded drugs did not create any harm or risk to Mr. Lapiska and others who received the compounded medication.

115. In breach of those duties, Defendants failed to exercise due care and failed to supervise their employee(s) or agent(s), who were at all times working within the scope of their employment and authority. Specifically, and without limitation:

- a. The Defendants failed to monitor and test the steroid medication and were otherwise negligent in supervision of their employees.
- b. Defendants also failed to monitor and supervise the testing of the compounded medications.
- c. The Defendants were negligent in hiring, training, and supervising their employees.

116. The Defendants knew, or should have known, that their employee(s) or agent(s) did not follow proper procedures and knew or should have known of the risks created by failing to do so.

117. As a direct and proximate cause of the breach of those duties, the Defendants permitted the steroid to become contaminated and distributed to patients including Mr. Lapiska.

118. The aforementioned acts or omissions by Ameridose, MSM/MSMSW, GDC, ARL, Barry Cadden, Gregory Conigliaro, Lisa Cadden, Douglas Conigliaro, Carla Conigliaro and Glenn Chin were a proximate cause of Mr. Lapiska's injuries and damages.

**COUNT IV - PUBLIC NUISANCE**  
(Against Barry Cadden, Gregory Conigliaro and GDC)

119. At all relevant times, Barry Cadden, Gregory Conigliaro and/or GDC were in control of the property and improvements at 697 Waverly Street, Framingham, Massachusetts.

120. Barry Cadden, Gregory Conigliaro and GDC owed a duty to maintain the property and improvements at 697 Waverly Street, Framingham, Massachusetts in a condition that was free from contamination.

121. Barry Cadden, Gregory Conigliaro and GDC failed to exercise reasonable care in maintaining the property and improvements at 697 Waverly Street, Framingham, Massachusetts.

122. The failure by Barry Cadden, Gregory Conigliaro and GDC to maintain the property and improvements at 697 Waverly Street, Framingham, Massachusetts was a proximate cause of the multistate epidemic of fungal meningitis and infections caused by the contaminated MPA.

123. Barry Cadden, Gregory Conigliaro and GDC unreasonably and significantly interfered with the public health and the public safety.

124. Barry Cadden, Gregory Conigliaro and GDC unreasonably and significantly interfered with the public right expressed in 247 CMR 6.02(1).

125. The public nuisance created by Barry Cadden, Gregory Conigliaro and GDC was a proximate cause of Mr. Lapiska's injuries and damages.

126. The public nuisance created by Barry Cadden, Gregory Conigliaro and GDC has caused Mr. Lapiska special injury in that he has sustained injuries to his personal health.

**COUNT V - PRODUCT LIABILITY CLAIMS**  
(Against Specialty Surgery)

127. The MPA injected into Mr. Lapiska on July 18 and September 18, 2012 was compounded by NECC.

128. On December 21, 2012, NECC filed a voluntary petition pursuant to Chapter 11 of Title 11 of the United States Bankruptcy Code in the United States Bankruptcy Court for the District of Massachusetts, In re: New England Compounding Pharmacy, Inc., No. 12-19882-HJB.

129. Pursuant to 11 U.S.C. § 362(a) (1) certain actions against NECC are stayed following its bankruptcy petition.

130. Mr. Lapiska's claims that arose before NECC's petition in bankruptcy are subject to the automatic stay provisions of 11 U.S.C. § 362(a) (1).

131. NECC has ceased operations.

132. NECC is unable to pay its debts as they fall due.

133. NECC is unable to pay its debts in the ordinary course of its business.

134. NECC's liabilities exceed its assets.

135. NECC is insolvent.

136. On July 24, 2013, the United States Bankruptcy Court for the District of Massachusetts in In re: New England Compounding Pharmacy, Inc., No. 12-19882-HJB, ordered that with respect to certain claims, including those asserted here, NECC is presently insolvent and has been insolvent at all times since the petition date.

137. Specialty Surgery procured the MPA injected into Mr. Lapiska from NECC.

138. NECC's product was defective and unreasonably dangerous when it left NECC's control because it was contaminated with lethal pathogens, and it was in substantially the same condition at the time that Specialty Surgery injected it into Mr. Lapiska on July 18 and September 18, 2012.

139. Specialty Surgery charged Mr. Lapiska for epidural steroid injections it administered to him.

140. Specialty Surgery acted as a seller or distributor of MPA compounded by NECC when it sold and administered epidural steroid injections to patients, including Mr. Lapiska.

141. Specialty Surgery was engaged in the business of selling MPA compounded by NECC.

142. Accordingly, Specialty Surgery is a “seller” as defined by Tenn. Code Ann. § 29-28-102(7).

143. Tenn. Code Ann. § 29-28-106(4) and/or (5) authorizes Mr. Lapiska to prosecute product liability claims against Specialty Surgery as the seller of the MPA injected into Mr. Lapiska because the compounder of the product, NECC, cannot be served with process in this state and/or has been or will be judicially declared insolvent.

144. The MPA that Specialty Surgery injected into Mr. Lapiska was unreasonably dangerous and defective at the time it left its control because it was contaminated with lethal pathogens.

145. Specifically, the MPA was in a defective condition and unreasonably dangerous at all relevant times because it was unsafe for normal or anticipated handling as defined by Tenn. Code Ann. § 29-28-102(2).

146. The MPA sold and distributed by Specialty Surgery was neither merchantable nor fit for the purpose for which it was produced and sold. Accordingly, Specialty Surgery breached its warranties, both express and implied, as stated in Tenn. Code Ann. §§ 47-2-313, 47-2-314 and 47-2-315, including its warranty of fitness for a particular purpose.

147. Specialty Surgery is strictly liable for the injuries and losses caused by the unreasonably dangerous and defective steroids injected into Mr. Lapiska.

### **DAMAGES**

148. As a direct and proximate result of the Defendants’ wrongful conduct as described above, Mr. Lapiska has suffered physical injuries, physical and mental pain and suffering, mental anguish, and loss of enjoyment of life.

149. The long term effects of Mr. Lapiska’s condition are unknown.

150. Mr. Lapiska remains under the care of physicians and has incurred and will continue to incur medical and other expenses.

**PUNITIVE DAMAGES**

151. The above described acts and omissions on the part of the Defendants were reckless and intentional. Defendants were aware of, but consciously disregarded, a substantial and unjustifiable risk of such a nature that their disregard constitutes a gross deviation from the standard of care that an ordinary person would exercise under all the circumstances. Mr. Lapiska is therefore entitled to an award of punitive damages against the Defendants.

**CAPS FOUND IN TENN. CODE ANN. § 29-39-102 AND § 29-39-104  
ARE UNCONSTITUTIONAL AND VOID *AB INITIO***

152. On October 1, 2011, the Tennessee Civil Justice Act went into effect, enacting “caps” in all Tennessee personal injury cases for non-economic damages and punitive damages. Tenn. Code Ann. § 29-39-102; and Tenn. Code Ann. § 29-39-104. Under that Act, Mr. Lapiska’s non-economic damages are purportedly capped at \$750,000, and his ability to recover punitive damages is capped at twice the compensatory damages up to a maximum of \$500,000.

153. Tenn. Code Ann. § 29-39-102 and Tenn. Code Ann. § 29-39-104 are unconstitutional deprivations of Mr. Lapiska’s constitutionally protected right to trial by jury. Those provisions violate Article I, Section 6 of the Constitution of the State of Tennessee, which provides that the right of trial by jury shall remain inviolate. In addition, the subject statutory caps violate Article I, Section 17 of the Tennessee Constitution which states that all courts shall be open, and every man shall have a remedy for injury done by due course of law and without denial or delay. The subject statutory caps usurp the powers of the Judicial Branch in violation of Article II, Sections 1 & 2 of the Tennessee Constitution. In addition, the subject statutory caps violate Article XI, Section 16 of the Tennessee Constitution which indicates that the rights of



citizens articulated in Tennessee's Bill of Rights "shall never be violated on any pretense whatever . . . and shall forever remain inviolate." Therefore, Mr. Lapiska requests a declaration, pursuant to Tenn. Code Ann. § 29-14-103, that the statutory caps are void *ab initio* and of no force and effect.

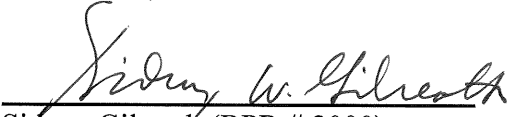
154. Pursuant to Tenn. Code Ann. § 29-14-107, a copy of this Complaint is being served on the Attorney General of the State of Tennessee, notifying the State of Tennessee Attorney General that Mr. Lapiska is challenging the constitutionality of Tenn. Code Ann. § 29-39-102 and Tenn. Code Ann. § 29-39-104.

**PRAYER FOR RELIEF**

WHEREFORE, Plaintiff, William Lapiska, requests the following relief:

- A. A judgment for compensatory damages in an amount to be determined by the trier of fact;
- B. A judgment for punitive damages in an amount to be determined by the trier of fact;
- C. A jury to determine all disputed factual issues;
- D. For costs of this cause; and
- E. For such further relief as the Court may deem just and proper.

Respectfully submitted,

  
Sidney Gilreath (BPR # 2000)  
Timothy A. Housholder (BPR # 020792)  
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*Attorneys for Plaintiff*

**UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF MASSACHUSETTS**

<b>WILLIAM LAPISKA</b>	:	<b>CIVIL ACTION NO. 1:13-cv-12914-FDS</b>
<b>Plaintiff,</b>	:	<b>MDL No. 2419</b>
<b>v.</b>	:	<b>Master Docket No. 1:13-md-2419-FDS</b>
<b>UNIFIRST CORPORATION, D/B/A</b>	:	<b>Honorable F. Dennis Saylor</b>
<b>UNICLEAN CLEANROOM</b>	:	
<b>SERVICES, <sup>and</sup> SPECIALTY</b>	:	<b><u>DEMAND FOR JURY TRIAL</u></b>
<b>SURGERY CENTER, PLLC D/B/A</b>	:	
<b>SPECIALTY SURGERY CENTER,</b>	:	
<b>Defendants.</b>	:	

**SHORT FORM COMPLAINT  
AGAINST UNAFFILIATED DEFENDANTS**

Plaintiff William Lapiska, complaining against Defendants, alleges as follows:

**FIRST COUNT**

1. Pursuant to MDL Order No. 7, entered in In Re: New England Compounding Pharmacy, Inc. Products liability Litigation, Master Docket No. 1:13-md-2419-FDS, the undersigned counsel hereby submit this Short Form Complaint and Jury Demand against Defendants, and adopt and incorporate by reference the allegations in Plaintiffs' Master Complaint, with attachments, and any and all amendments thereto.

2. Plaintiff William Lapiska is a resident of the State of Tennessee.

3. Plaintiff William Lapiska brings this action:

☒ On behalf of himself.

☐ As the representative of \_\_\_\_\_, who is a living person.

☐ As the Administrator, Administrator ad Prosequendum, or other representative of the Estate of \_\_\_\_\_ (hereinafter “Decedent”), who died on \_\_\_\_\_.

4. **Intentionally Omitted.**

5. Plaintiff asserts he was administered New England Compounding Pharmacy, Inc. (“NECC”) drug methylprednisolone acetate (hereinafter referred to as “NECC drug”), causing injuries and damages.

6. The aforesaid administration of the NECC drug occurred on July 18 and September 18, 2012, by Kenneth Lister, M.D. at Defendant Specialty Surgery Center, PLLC d/b/a Specialty Surgery Center (“Clinic Related Defendant”), located in Crossville, Tennessee.

7. **Intentionally Omitted.**

8. Plaintiff adopts and incorporates by reference the following Causes of Action asserted against Defendants in the Master Complaint:

- ☒ COUNT II: NEGLIGENCE AND GROSS NEGLIGENCE (Against UniFirst)
- ☒ COUNT III: NEGLIGENCE AND GROSS NEGLIGENCE (Against Clinic Related Defendant)
- ☐ COUNT IV: VIOLATION OF CONSUMER PROTECTION STATUTES (Against Clinic Related Defendants)

Plaintiff(s) allege violation of the following consumer protection statute(s): [List statutes. Note that N.J.S.A. 56:8-1 *et seq.* was inadvertently omitted from the Master Complaint]

- ☐ COUNT VI: VIOLATION OF M.G.L. C. 93A (Against UniFirst)
- ☐ COUNT VII: BATTERY (Against Clinic Related Defendants)
- ☒ COUNT VIII: FAILURE TO WARN (Against Clinic Related Defendant)

- ☒ COUNT IX: TENNESSEE PRODUCT LIABILITY CLAIMS (Against Clinic Related Defendant)
- ☐ COUNT X: AGENCY (Against Clinic Related Defendants)
- ☐ COUNT XI: CIVIL CONSPIRACY (Against Clinic Related Defendants)
- ☐ COUNT XII: WRONGFUL DEATH PUNITIVE DAMAGES (Against UniFirst and Clinic Related Defendants)
- ☐ COUNT XIII: LOSS OF CONSORTIUM (Against UniFirst and Clinic Related Defendant)
- ☒ COUNT XIV: PUNITIVE DAMAGES (Against UniFirst and Clinic Related Defendant)

9. **Intentionally Omitted.**

10. On or about September 10, 2013, Plaintiff gave pre-suit notice of his potential medical malpractice claim to Clinic Related Defendants and, in doing so, extended Tennessee's one (1) year medical malpractice statute of limitations by 120 days to at least January 8, 2013, or as late as February 4, 2014 pursuant to application of the discovery rule under Tennessee law. Accordingly, Plaintiff expressly reserves his rights to amend his Complaint to add allegations of medical malpractice under and in conformity with Tennessee's medical malpractice act, Tenn. Code Ann. § 29-26-101, et seq. On or about December 19, 2013, Plaintiff sent or served pre-suit notice or demand requirements necessary under M.G.L.C. 93A to bring a claim for violation of M.G.L.C. 93A (as set forth in Count VI of the Master Complaint) and will seek leave to assert such claim promptly after the time period for giving notice has expired.

11. Plaintiff William Lapiska has suffered and continues to suffer physical injuries (including multiple invasive, painful medical tests including spinal taps, MRI's, back pain and stiffness, fungal infection presenting as an inter-spinal abscess, surgery and hospitalization), physical and mental pain and suffering, mental anguish, loss of enjoyment of life, and loss of

opportunity to be treated for back pain management with steroidal injections as a result of the Defendants' negligent misconduct, acts, and omissions.

12. Plaintiff William Lapiska suffered and continues to suffer the following damages as a result of the administration of NECC's drug(s): pain and suffering, mental anguish, emotional distress, past and future medical care and treatment, loss of enjoyment of life, and medical expenses, both past and future.

13. **Intentionally Omitted.**

Plaintiff reserves the right to amend this Complaint to add allegations and claims against individuals or entities currently omitted (in light of the Court's order permitting a Master Complaint naming defendants affiliated with NECC and currently participating in mediation by December 20) and to add or amend allegations against Defendants named herein based, in part, on further discovery.

WHEREFORE, Plaintiffs demands Judgment against Defendants awarding compensatory damages, punitive damages, attorneys' fees, interest, costs of suit, and such further relief as the Court deems equitable and just. Pursuant to Tenn. Code Ann. § 29-28-107, Plaintiff prays for damages in an amount not to exceed \$1,000,000.00.

**SECOND COUNT**

14. Plaintiff re-alleges and incorporates by reference each of the foregoing paragraphs as if set forth at length herein.

15. Plaintiffs incorporate all allegations and counts contained in Plaintiffs' Original Complaint found at Docket No. 1, in the litigation styled William Lapiska v. Ameridose LLC, et al.; United States District Court, District of Massachusetts, 1:13-cv-12914, (MDL No. 1:13-md-

2419-FDS) together with all prayers for relief stated therein.

16. Plaintiff William Lapiska has suffered and continues to suffer injuries as set forth in Paragraph 11 herein.

17. Plaintiff William Lapiska has suffered and continues to suffer damages as set forth in Paragraph 12 herein.

18. **Intentionally Omitted.**

WHEREFORE, Plaintiff demands Judgment against Defendants awarding compensatory damages, punitive damages, attorneys' fees, interest, costs of suit, and such further relief as the Court deems equitable and just.

### **JURY DEMAND**

Plaintiff hereby demands a trial by jury.

Respectfully submitted, this 20<sup>th</sup> day of December, 2013.

/s/ Timothy Housholder  
Timothy Housholder (BPR # 020792)  
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[thousholder@sidgilreath.com](mailto:thousholder@sidgilreath.com)  
*Attorney for Plaintiff*

### **CERTIFICATE OF SERVICE**

I hereby certify that on December 20, 2013, a true and exact copy of the foregoing was filed electronically. Notice of this filing will be sent by operation of the Court's electronic filing system to all parties indicated on the electronic filing receipt. Parties may access this filing through the Court's electronic filing system.

/s/ Timothy Housholder

**IN THE UNITED STATES DISTRICT COURT  
MIDDLE DISTRICT OF TENNESSEE**

DARWIN L. NEALON, AS SON, NEXT OF KIN TO  
AND AS THE ADMINISTRATOR OF THE ESTATE  
OF DALLAS RAY NEALON, DECEASED

Plaintiff,

v.

AMERIDOSE, LLC, MEDICAL SALES  
MANAGEMENT, INC., MEDICAL SALES  
MANAGEMENT SW, INC., GDC  
PROPERTIES MANAGEMENT, LLC,  
ARL BIO PHARMA, INC. d/b/a  
ANALYTICAL RESEARCH LABORATORIES,  
BARRY J. CADDEN, GREGORY CONIGLIARO,  
LISA CONIGLIARO CADDEN, DOUGLAS  
CONIGLIARO, CARLA CONIGLIARO,  
GLENN A. CHIN, and SPECIALTY SURGERY  
CENTER, LLC

Defendants.

Case No. \_\_\_\_\_

**JURY DEMAND**

**COMPLAINT**

Plaintiff, Darwin L. Nealon, as Son, Next of Kin to and as Administrator of the Estate of Dallas Ray Nealon, Deceased, for his cause of action against the Defendants respectfully states to the Court as follows:

**INTRODUCTION**

1. This lawsuit arises as a result of a widespread outbreak of fungal meningitis over the past year that has affected people in at least 20 states and caused over 60 deaths. Over 700 people have been diagnosed with meningitis and/or fungal infections.

2. The United States Food and Drug Administration ("FDA") and the Centers for Disease Control ("CDC") have identified fungus present in several separate lots of preservative free injectable steroids, specifically methylprednisolone acetate (sometimes hereinafter referred to as "MPA"), that was compounded and distributed by New England Compounding Pharmacy, Inc., d/b/a New England Compounding Center (hereinafter "NECC") as the cause of the fungal meningitis outbreak and the resulting injuries and deaths.



3. Multiple vials of steroids compounded at NECC have been recalled but the recall was too late for the Plaintiff's Decedent Dallas Ray Nealon, and for many others who have suffered serious and at times catastrophic injuries and death.

4. During 2012, Specialty Surgery Center, PLLC, ("Specialty Surgery Center") purchased vials of MPA from NECC and then sold and administered the MPA to patients, including to the Plaintiff's Decedent Dallas Ray Nealon.

5. Plaintiff's Decedent Dallas Ray Nealon suffered from chronic pain due to degenerative diseases of his spine. Plaintiff's Decedent Dallas Ray Nealon received epidural steroid injections on August 29, 2012 and September 26, 2012, at Specialty Surgery Center. During these procedures the anesthesiologist injected MPA purchased from NECC into the Decedent Dallas Ray Nealon's spine.

6. Decedent Dallas Ray Nealon's epidural steroid injections on August 29, 2012 and September 26, 2012, came from contaminated lots of MPA that were purchased from NECC. The contaminated lots were subsequently recalled by NECC.

7. Decedent Dallas Ray Nealon's injections of MPA caused him to suffer fungal meningitis and severe complications related thereto, which eventually caused the wrongful death of Dallas Ray Nealon.

#### **PARTIES**

8. The Plaintiff Darwin L. Nealon is a citizen and resident of Ohio and he resides at 1260 Crosscreek Drive, Apt. 71, Brunswick, Ohio, 44212, in Medina County, Ohio. At the time of his death, Plaintiff's Decedent Dallas Ray Nealon was a citizen and resident of Tennessee and he resided at 90 Adelaide Street, Crossville, Tennessee, 38555, in Cumberland County. Dallas Ray Nealon died at Cookeville Regional Medical Center in Putnam County, Tennessee. By Order of the Honorable Larry M. Warner, Judge of the Probate and Family Court of Cumberland County Tennessee, entered on August 1, 2013, Darwin L. Nealon was appointed Administrator *ad litem* of the Estate of Dallas Ray Nealon, for the limited purpose of a cause of action only [copy of that Order is attached as Exhibit "A"].

9. Defendant Ameridose, LLC, ("Ameridose") is a Massachusetts limited liability company organized and domesticated under the laws of the Commonwealth of Massachusetts with a principal place of business at 205 Flanders Road, Westborough, Massachusetts, 01581. The managers of Ameridose are Gregory Conigliaro and Barry Cadden. Ameridose's registered agent, is Gregory Conigliaro.

10. Defendant Medical Sales Management, Inc., ("MSM") is a Massachusetts corporation organized and domesticated under the laws of the Commonwealth of Massachusetts with its principal place of business at 697 Waverly Street, Framingham, Massachusetts, 01702. Douglas Conigliaro is the President and a Director of MSM. Barry Cadden is the Treasurer and a Director of MSM. Gregory Conigliaro is the Secretary and a Director of MSM. MSM's registered agent is Gregory Conigliaro.

11. Defendant Medical Sales Management SW, Inc., ("MSMSW") is a Massachusetts corporation organized and domesticated under the laws of the Commonwealth of Massachusetts with its principal place of business at 697 Waverly Street, Framingham, Massachusetts, 01702. Douglas Conigliaro is the President and a Director, Barry Cadden is the Treasurer and a Director, Gregory Conigliaro is the Secretary and a Director and Lisa Conigliaro Cadden is a Director. MSMSW's registered agent is Gregory Conigliaro.

12. Defendant GDC Properties Management, LLC, ("GDC") is a Massachusetts limited liability company organized and domesticated under the laws of the Commonwealth of Massachusetts with its principal place of business at 701 Waverly Street, Framingham, Massachusetts, 01702. GDC's manager and registered agent is Gregory Conigliaro.

13. Defendant ARL Bio Pharma, Inc. d/b/a Analytical Research Laboratories ("ARL") is an Oklahoma corporation organized and domesticated under the laws of the State of Oklahoma with a principal place of business at 840 Research Parkway, Suite 546, Oklahoma City, Oklahoma, 73104. Thomas C. Kupiec is the Chief Executive Officer and registered agent of ARL.

14. Defendant Barry J. Cadden ("Barry Cadden") is an individual residing at 13 Manchester Drive, Wrentham, Massachusetts, 02093, and a citizen and resident of the Commonwealth of Massachusetts.

Barry Cadden is the President of New England Compounding Pharmacy, Inc., d/b/a New England Compounding Center ("NECC"), which is a Massachusetts corporation. At least until October 2012, Barry Cadden was NECC's licensed Pharmacist Manager of Record. Barry Cadden is a founder and Manager of Ameridose and was involved in Ameridose's day to day operations. Barry Cadden is the Treasurer and Director of MSM and MSMSW.

15. Defendant Gregory Conigliaro ("Gregory Conigliaro") is an individual residing at 1 Mountain View Drive, Framingham, Massachusetts, 01701, and a citizen and resident of the Commonwealth of Massachusetts. Gregory Conigliaro is a principal owner and the general manager of NECC, as well as NECC's Treasurer, Secretary, Vice President, registered agent, and one of its Directors. Gregory Conigliaro provided financial advice, oversaw day to day operations, and regularly appeared in the NECC facility. Gregory Conigliaro is the founder and a Manager of Ameridose and involved in Ameridose's day to day operations. Gregory Conigliaro is Secretary and Director of MSM and MSMSW.

16. Defendant Lisa Conigliaro Cadden ("Lisa Cadden") is an individual residing at 13 Manchester Drive, Wrentham, Massachusetts, 02093, and a citizen and resident of the Commonwealth of Massachusetts. Lisa Cadden is a board member, Director and, at least until October 2012, a pharmacist at NECC. Lisa Cadden, upon information and belief, compounded drugs and was involved in the day to day operations of NECC.

17. Defendant Douglas Conigliaro ("Douglas Conigliaro") is an individual residing at 15 Hale Drive, Dedham, Massachusetts, 02026, and a citizen and resident of the Commonwealth of Massachusetts. Douglas Conigliaro is the President and a Director of MSM and MSMSW. Douglas Conigliaro, upon information and belief, is involved in the day to day operations of NECC, Ameridose, MSM, and MSMSW.

18. Defendant Carla Conigliaro ("Carla Conigliaro") is an individual residing at 15 Hale Drive, Dedham, Massachusetts, 02026, and a citizen and resident of the Commonwealth of Massachusetts and is a Director of NECC.

19. Defendant Glenn A. Chin ("Glenn Chin") is an individual residing at 173 Mechanic Street, Canton, Massachusetts, 02021, and a citizen and resident of the Commonwealth of Massachusetts. At least until October 2012, Glenn Chin was a pharmacist at NECC. Glen Chin, upon information and belief, compounded drugs at NECC.

20. Defendant Specialty Surgery Center, PLLC, ("Specialty Surgery Center") is a Tennessee for-profit limited liability company organized and domesticated under the laws of the State of Tennessee. Specialty Surgery Center's principal place of business is located at 116 Brown Avenue, Crossville, TN 38555 in Cumberland County, Tennessee. Specialty Surgery Center's registered agent for service of process is Donathan M. Ivey, at 116 Brown Avenue, Crossville, TN 38555-7703.

21. At all times while providing and selling drug products to the Decedent Dallas Ray Nealon at Specialty Surgery Center, the physicians, nurses, staff, and other personnel were agents, apparent agents, employees or representatives of Specialty Surgery Center and were acting within the course and scope of their employment, agency, or apparent agency with Specialty Surgery Center.

22. Pursuant to the doctrine of *respondeat superior*, Specialty Surgery Center is vicariously liable for any negligent acts and omissions of their employees, agents, or representatives committed in the course and scope of their employment or agency while providing and selling drug products to the Decedent Dallas Ray Nealon.

23. The individuals and entities described in paragraphs 9-19 are sometimes collectively referred to as the "NECC Related Defendants."

24. Specialty Surgery Center is sometimes referred to as the "Tennessee Defendant."

#### **JURISDICTION AND VENUE**

25. This Court has subject matter jurisdiction over the parties pursuant to 28 U.S.C. § 1334(b) because as described herein each claim asserted herein is related to a case under title 11.

26. This case is related to the NECC Bankruptcy because the outcome of the proceeding certainly could have some effect on the bankruptcy estate.

27. On December 21, 2012, NECC filed a petition for Bankruptcy protection under Chapter 11 of the Bankruptcy Code: In re: New England Compounding Pharmacy, Inc., Debtor, United States Bankruptcy Court for the District of Massachusetts Case no. 12:19882 HJB. A United States Trustee was subsequently appointed to administer the Bankruptcy Estate.

28. NECC has express contractual indemnification obligations to among others, Barry Cadden, Gregory Conigliaro, Lisa Cadden, Carla Conigliaro, Glenn Chin, GDC, and MSM. Some if not all of the aforementioned individuals are insureds under NECC's insurance policies.

29. Adversarial cases seeking recovery of damages for the benefit of the bankruptcy estate and its unsecured creditors have been filed in NECC's bankruptcy against each of the NECC Related Defendants.

30. Lawsuits alleging death or injury based on contaminated MPA have been filed around the country. On February 12, 2013, the Judicial Panel on Multi-district Litigation (MDL No. 2419) issued an order under 28 U.S.C. § 1407 transferring various federal court proceedings to the United States District Court for the District of Massachusetts for coordinated or consolidated pretrial proceedings. The transferred actions are pending in the United States District Court for the District of Massachusetts in the Multi-district Litigation action styled: In re: New England Compounding Pharmacy, Inc. Products Liability Litigation, United States District Court, District of Massachusetts, MDL No. 1:13-md-2419-FDS. The transferred cases have been assigned to the Honorable F. Dennis Saylor, United States District Judge, for pre-trial proceedings and coordination.

31. The Bankruptcy Court for the District of Massachusetts has not yet established a deadline for the filing of claims against NECC's bankruptcy estate In re: New England Compounding Pharmacy, Inc.

32. Upon information and belief, the Tennessee Defendant Specialty Surgery Center presently intends to seek, and will seek, relief from the stay in order to pursue contribution or indemnity claims against NECC for all or some portion of the damages sought by this Complaint. In addition or in the alternative, the Tennessee Defendant presently intends to file, and will file, claims in NECC's bankruptcy proceeding seeking indemnification or contribution for all or some portion of the damages sought by this Complaint.

33. The Plaintiff has filed a proof of claim against NECC in its bankruptcy proceeding for the injuries at issue in this Complaint.

34. By Order dated May 31, 2013, Judge Saylor, ruled that the New England Compounding Pharmacy, Inc., Multi District Litigation Court has subject matter jurisdiction over any cases pending in federal court or state court against entities or individuals "affiliated" with NECC whether or not NECC is named as a defendant. Those NECC affiliated entities and individuals referred to by Judge Saylor in his May 31, 2013, Order include the defendants described in paragraphs 9-19.

35. In addition, or in the alternative to the bases for jurisdiction already asserted, this Court has subject-matter jurisdiction over all claims against the Tennessee Defendant pursuant to 28 U.S.C. § 1367, in that all such claims are so related to claims in this action within the original jurisdiction of this Court that they form part of the same case or controversy under Article III of the United States Constitution.

36. Venue is proper and appropriate in the United States District Court for the Middle District of Tennessee pursuant to 28 U.S.C. § 1391(b)(2) in that all or a substantial part of the events and actions giving rise to the matters asserted in the Complaint occurred in Cumberland County, Tennessee.

37. At all times relevant the Defendants were engaged in the business of developing, compounding, marketing, distributing, promoting, selecting, purchasing, and/or selling or administering, either directly or indirectly, steroids in the State of Tennessee, from which they derived significant and regular income or profit.

38. Defendants are subject to the jurisdiction of this Court in that they are generally present in Tennessee, have transacted business within the State of Tennessee, and acting individually and/or through their managers, agents and employees, have committed tortious acts and omissions in Cumberland County, Tennessee, that have proximately caused the injuries and damages that are the subject of this lawsuit.

39. The NECC Related Defendants described in paragraphs 9-19 are further subject to the jurisdiction of this Court as a result of contracting to supply goods and things in Tennessee, by conducting or soliciting business in Tennessee, by engaging in a persistent course of conduct in Tennessee, and by deriving substantial revenue from goods used or consumed or services rendered in Tennessee.

**STATEMENT OF FACTS**

**Relevant background**

40. NECC is an entity that has filed for bankruptcy and is protected by the automatic stay provisions of 11 U.S.C. § 362.

41. NECC was a compounding pharmacy that compounded, distributed, and/or sold drugs to purchasers throughout the United States, including Tennessee.

42. Upon information and belief, NECC was a privately held company that was owned and controlled by Barry Cadden, Gregory Conigliaro, Douglas Conigliaro, Carla Conigliaro and Lisa Cadden.

43. Ameridose, GDC, MSM, and MSMSW were affiliates of NECC at all relevant times.

44. At least until October 2012, Gregory Conigliaro was involved in co-managing day-to-day operations of NECC, MSM, MSMSW, Ameridose, and GDC.

45. At least until October 2012, Lisa Cadden was a licensed pharmacist who, upon information and belief, compounded medications including MPA at NECC.

46. At least until October 2012, Glenn Chinn was a licensed pharmacist who, upon information and belief, compounded medications including MPA at NECC.

47. At least until October 2012, Barry Cadden was a licensed pharmacist. In addition to being NECC's President, Barry Cadden was NECC's licensed Pharmacist Manager of Record. Upon information and belief, Barry Cadden compounded medications including MPA at NECC.

48. "Manager of Record or Pharmacist Manager of Record," as defined by 247 CMR 2.00, "means a pharmacist, currently registered by the [Massachusetts] Board [of Registration in Pharmacy] pursuant to 247 CMR 6.07, who is responsible for the operation of a pharmacy or pharmacy department in conformance with all laws and regulations pertinent to the practice of pharmacy and the distribution of drugs."

49. Ameridose, according to an application signed by Gregory Conigliaro and filed with the Massachusetts Board of Registration in Pharmacy on May 14, 2012, is a "distribution center to entities of common ownership - currently Ameridose and NECC, as well as other Properly Licensed Facilities in the future."



50. Upon information and belief, and upon the direction of NECC's principals, on April 11, 2011, Ameridose employee Michelle Rivers requested certification for pharmacy technicians employed by NECC for use in an inspection of NECC's facilities by the Massachusetts Board of Registration in Pharmacy.

51. On or about August 24, 2012, Ameridose posted an employment opportunity for Registered Pharmacists to work for NECC in Framingham, Massachusetts. In the posting, potential applicants were told to contact [mlord@medicalesalesmgmt.com](mailto:mlord@medicalesalesmgmt.com). Upon information and belief, there were many other occasions where employees of Ameridose, MSM and/or MSMSW would perform services for NECC at the direction of NECC's principals.

52. Between 2006 and the present, Ameridose and NECC would often share a booth at conferences and conventions with a single banner listing both company names. During that same time, Ameridose and NECC would hold an annual Christmas party for employees of both companies.

53. MSM and/or MSMSW printed materials for and marketed both NECC's and Ameridose's products, including methylprednisolone acetate. One former employee of MSM and/or MSMSW has stated: "I didn't think there was any difference [between Ameridose and NECC]."

54. Through September 2012, both NECC and Ameridose used MSM and/or MSMSW for sales and marketing functions. NECC's privacy policy on its website referred to the "Ameridose Privacy Policy." In 2012, NECC salespersons recommended NECC's "sister company," Ameridose, for drug compounds that NECC did not have available.

55. MSM and/or MSMSW shared office space owned by GDC Properties with NECC in Framingham, Massachusetts.

56. Since it was formed as a limited liability company in 2006, Ameridose has been controlled by NECC.

57. Both Ameridose and NECC were controlled by Conigliaro and Cadden family members.



**Claims Against the NECC Related Defendants**

58. NECC has a well known history of adverse events relating to its operation as a compounding pharmacy. According to the Majority Memorandum for the November 14, 2012, Oversight and Investigations Subcommittee Hearing, NECC has been the subject of multiple complaints to and investigations by the FDA and the Massachusetts Board of Registration in Pharmacy ("MBP") over the past decade often focusing on unsterile conditions at NECC's facilities. For example, the FDA issued a Warning Letter to NECC in 2006. The FDA letter details numerous problems at NECC including the sale of compounded drugs without patient specific prescriptions, compounding copies of commercially available drugs, selling mis-branded compounded drugs, and problems with storage and sterility. That warning letter has been available to the public on the FDA's website for years.

59. Between January 2012 and August 2012, NECC's environmental monitoring program for its compounding facility yielded numerous microbiological isolates (bacteria and mold) within the Clean Room used for the production of methylprednisolone acetate. NECC, Barry Cadden, Gregory Conigliaro, Lisa Cadden, Douglas Conigliaro, Carla Conigliaro, Glenn Chin, Ameridose, MSM and/or MSMSW, and GDC knew or should have known of these findings. NECC, Barry Cadden, Gregory Conigliaro, Lisa Cadden, Douglas Conigliaro, Carla Conigliaro, Glenn Chin, Ameridose, MSM and/or MSMSW, and GDC failed to investigate those isolates and made no effort to identify those isolates. NECC, Barry Cadden, Gregory Conigliaro, Lisa Cadden, Douglas Conigliaro, Carla Conigliaro, Glenn Chin, Ameridose, MSM and/or MSMSW, and GDC failed to perform any product assessments for the products made in the Clean Room where the isolates were found. NECC, Barry Cadden, Gregory Conigliaro, Lisa Cadden, Douglas Conigliaro, Carla Conigliaro, Glenn Chin, Ameridose, MSM and/or MSMSW, and GDC failed to take any corrective actions with regards to the isolates that were found. Despite these findings, NECC continued to compound methylprednisolone acetate, and Ameridose, MSM, and/or MSMSW continued to distribute marketing materials to customers and potential customers touting the cleanliness of the NECC laboratories.

60. On September 26, 2012, in the wake of dozens of cases of fungal meningitis associated with NECC's injectable steroid MPA, state agents raided NECC's lab in a strip mall on Waverly Street in Framingham, Massachusetts.

61. NECC's few remaining employees were scrubbing the compounding areas with bleach. Despite this last-ditch effort, the "clean" rooms were filthy. A leaky boiler stood in a pool of stagnant, dirty water. The autoclaves used to sterilize the product were discolored, tarnished, and contained visible moisture. The air intake came from vents located about 100 feet from a mattress recycling facility that released copious amounts of dust and other contaminants into the air. The air vents in the "clean" rooms were covered with dirt and white fuzz. The metal shelf in the "clean" room used to prepare methylprednisolone acetate was covered in a reddish-brown, cloudy substance.

62. Investigators determined that NECC's internal records showed dozens of instances of bacterial and fungal contamination within the NECC facility over at least the past nine months. NECC ignored these test results. NECC never even attempted to get rid of these microbial contaminants.

63. Eighty-three out of three hundred twenty-one observed vials from one of three recalled lots of NECC compounded MPA contained a greenish-black substance visible to the human eye. Seventeen other vials contained a white filamentous material. All fifty out of fifty vials tested confirmed the presence of live microbes (whether fungal or bacterial). The CDC and FDA later confirmed the presence of fungus in unopened vials of NECC's methylprednisolone acetate. This is the same fungus that the CDC confirmed was present in at least forty fungal meningitis cases.

64. Inspections of NECC's sister company Ameridose revealed similarly deplorable conditions, including countless instances of visible contamination of the hoods and rooms used to prepare drug products, insect infestations, birds flying through areas where purportedly sterile products were packaged and stored, and tubs being used to collect rain water that poured through the chronically leaky roof above the "clean" rooms. Ameridose, like NECC, persistently ignored and failed to investigate at least fifty-three instances of known microbiological contamination. Ameridose also hid adverse events associated with its products,

failing to report them to the FDA as required by law and instead classifying these events as "patient responses" or "non-complaints" and taking no action to address them.

65. The CDC determined that three lots of 80 mg/ml MPA produced by NECC between May 21 and September 26, 2012, were contaminated with potentially deadly pathogens.

66. In late September 2012, NECC recalled the following lots of methylprednisolone acetate (PF) 80 mg/ml that it had compounded and sold:

Methylprednisolone Acetate (PF) 80 mg/ml Injection, Lot # 05212012 @ 68, BUD 11/17/2012;  
Methylprednisolone Acetate (PF) 80 mg/ml Injection, Lot # 06292012 @ 26, BUD 12/26/2012;  
Methylprednisolone Acetate (PF) 80 mg/ml Injection, Lot # 08102012 @ 51, BUD 02/6/2013.

67. NECC identified Specialty Surgery Center in Crossville, Cumberland County, Tennessee, as one of the healthcare providers that received vials of methylprednisolone acetate that were part of the September 2012 recall.

68. On or about October 3, 2012, the Massachusetts Department of Public Health ("DPH") secured the surrender of NECC's license to operate as a compounding pharmacy.

69. On October 6, 2012, NECC announced that it was recalling "all products currently in circulation that were compounded at and distributed from its facility in Framingham, Massachusetts."

70. On or about October 8, 2012, at the request of DPH, Barry Cadden and Glenn Chin voluntarily ceased their practice as pharmacists. Lisa Cadden also has voluntarily ceased her practice as a pharmacist. Upon information and belief, none of them have practiced as a pharmacist since voluntarily ceasing their practice.

71. On or about October 22, 2012, the Massachusetts Board of Registration in Pharmacy authorized DPH to request the voluntary permanent surrender of the licenses of Barry Cadden, Glenn Chin, Lisa Cadden, and NECC. According to DPH, "[i]f the three pharmacists and NECC do not comply, the Board authorized staff to proceed with permanent revocation."

72. One of the Massachusetts regulations promulgated by the Massachusetts Board of Registration in Pharmacy pertinent to NECC's operation as a compounding pharmacy mandated that "[t]he

premises of the pharmacy or pharmacy department shall at all times be kept in a clean and sanitary manner."  
247 CMR 6.02(1).

73. Over the last ten years, ARL has conducted sterility testing on samples of methylprednisolone acetate compounded by NECC, including samples from Lot # 05212012 @ 68, BUD 11/17/2012; Lot # 06292012 @ 26, BUD 12/26/2012; and Lot # 08102012 @ 51, BUD 2/6/2013.

74. From May through August 2012, NECC sent several samples of its MPA to ARL for sterility testing. As one example, on May 21, 2012, NECC sent to ARL two 5 ml vials of methylprednisolone acetate from a batch of 6,528 vials that came from Lot # 05212012 @ 68, which had been compounded by NECC on May 21, 2012.

75. On May 22, 2012, ARL received and tested the two 5 ml vials of methylprednisolone acetate that NECC sent to ARL on or about May 21, 2012. ARL sent to NECC a Microbiology Report dated May 25, 2012, which stated that the two vials had been tested on May 22, 2012.

76. ARL's May 25, 2012, Microbiology Report to NECC stated that the "preliminary" results from the sterility test using test method USP 71 showed that the two 5 ml vials of methylprednisolone acetate that NECC sent to ARL on or about May 21, 2012, were "sterile." ARL's report to NECC further noted that the preliminary results were observed "after approximately 72 hours of incubation."

77. Pursuant to the protocols of test method USP 71, sterility testing on a batch of more than 6,000 vials of methylprednisolone acetate should have been conducted on at least 20 vials from the batch.

78. On or about August 10, 2012, NECC caused one 5 ml vial of methylprednisolone acetate to be sent to ARL for sterility testing from a batch of several thousand vials that are from Lot # 08102012 @ 51, BUD 2/6/2013.

79. The Microbiology Reports issued by ARL to NECC between May and September 2012 concerning the sterility testing of methylprednisolone acetate indicated that the sterility tests performed by ARL were conducted in compliance with USP 71.

80. During the summer of 2012, MSM and/or MSMSW sales representatives, on behalf of NECC and Ameridose, distributed copies of the May 25, 2012, ARL Microbiology Report concerning the testing of the vials of methylprednisolone acetate from Lot # 05212012 @ 68 to customers and/or potential customers in a packet of marketing materials intended to highlight the safety and sterility of the methylprednisolone acetate compounded by NECC.

81. ARL was aware of the risks posed by compounding pharmacies, specifically including the risks posed by NECC's compounding practices.

82. In 2002, ARL found that four samples of a steroid compounded by NECC were in fact contaminated with potentially deadly endotoxins.

83. ARL allowed compounding pharmacies such as NECC to submit an inadequate number of samples for sterility testing, which practice did not comply with USP 71 requirements.

84. GDC, which is an acronym for "Gregory D. Conigliaro" owns the real property and is responsible for maintenance and structural improvements at 685-705 Waverly Street, Framingham, Massachusetts.

85. From 1998 until at least October 2012, GDC leased a portion of the premises at Waverly Street to NECC, MSM and MSMSW.

86. In an on-line posting for a property management position at GDC, which appeared on or before October 25, 2012, GDC stated that it "owns an 88,000 square foot facility on seven acres in downtown Framingham. GDC currently has eight major tenants." GDC described one of the duties and responsibilities of the GDC property manager as follows: "Insure all tenants operate their businesses in accordance with facility, local [and] state ... rules and regulations."

87. GDC maintained a high degree of control over the premises leased by NECC.

88. Until October 2012, NECC, Ameridose, ARL, Barry Cadden, Lisa Cadden, and Glenn Chin compounded, tested, marketed and/or distributed methylprednisolone acetate.

89. GDC and Gregory Conigliaro knew that NECC was compounding preservative free methylprednisolone acetate at 697 Waverly Street, and further knew that this medication was injected into humans and was required to be sterile.

**NECC and the Risks of Pharmacy Compounding:**

90. The serious risks of pharmacy compounding were also the subject of considerable public discussion in the pharmacy community and the medical community before the subject fungal meningitis outbreak. The risks associated with compounded drugs have been known for years.

91. In 2002, the CDC published a report regarding at least two cases of fungal meningitis arising from contaminated medication used in epidural injections. The report concluded that "...purchasers of pharmaceuticals should determine if supplies are provided from a compounding pharmacy that ... follows appropriate measures to ensure that injectable products are free of contamination."

92. On March 24, 2005, USA Today published a front page article with the following headline: "Safety concerns grow over pharmacy-mixed drugs." That article discussed growing concern over the fact that drugs produced in bulk by compounding pharmacies are not FDA approved and are not subject to the same oversight as drugs produced by pharmaceutical companies.

93. In 2006, the FDA conducted a survey of compounded drug products. They collected thirty-six samples from compounding pharmacies across the United States during unannounced visits. Twelve of the 36 samples (33%) failed analytical testing. The FDA survey concluded "poor quality compounded drugs are a serious public health concern," as improperly compounded products have been linked to grave adverse events, including deaths."

94. In May 2007, the FDA published an article titled: "The Special Risks of Pharmacy Compounding." That article highlighted numerous adverse events involving compounded products. It also warned of the emergence of large scale compounding operations that were clearly operating outside of the bounds of traditional compounding practice.

95. In 2010, the FDA posted an educational video on YouTube regarding concerns over the quality of compounded drugs.

96. On November 5, 2010, the American Society of Anesthesiologists, the American Society of Health-System Pharmacists ("ASHP") and other medical societies published a joint report regarding drug shortages. That report included an article written by the ASHP stating as follows:

**Compounding pharmacies have also pursued the production of drugs that are in short supply. Caution is warranted because preparations from these pharmacies may not meet applicable state or federal standards (e.g., United States Pharmacopeia chapter 797 or FDA labeling requirements). The sources of raw materials used by compounding pharmacies have been questioned, and apparent lapses in quality control have resulted in serious patient injury, including death.**

**Compounding pharmacies may also present patient risks; several deaths have been associated with improperly sterilized compounded products.**

97. In May 2012, the CDC published a report regarding fungal infections arising from medications obtained from a compounding pharmacy. That report advised that "contamination of compounded sterile preparations has caused outbreaks. Since 1990, FDA has learned of approximately 200 adverse events associated with 71 compounded products."

#### **The Fungal Meningitis Outbreak**

98. In September 2012, health officials identified an outbreak of fungal meningitis. Investigators traced the outbreak to MPA compounded by NECC.

99. On September 18, 2012, a Vanderbilt University Medical Center clinician notified the Tennessee Department of Health of a patient with fungal meningitis who had received a series of epidural steroid injections at Saint Thomas Outpatient Neurosurgical Center. On that same date, Dr. Marion Kainer of the Tennessee Department of Health contacted St. Thomas Hospital and spoke with the hospital's Infection Preventionist, Candace Smith.



100. Dr. Kainer told personnel at St. Thomas Hospital that a sentinel event of concern had occurred in a patient who received epidural steroid injections at Saint Thomas Outpatient Neurosurgical Center. She requested information from the hospital about the procedure, and she requested that the hospital commence an inspection of the Saint Thomas Outpatient Neurosurgical Center clinic. She explained that the event required careful investigation, and she requested that the hospital watch for additional potential cases.

101. Two days later, on September 20, 2012, St. Thomas Hospital reported to the Tennessee Department of Health ("TDH") that two additional patients with meningitis and high levels of white blood cells of unknown cause reported to the hospital. Both of those patients had likewise received ESIs at Saint Thomas Outpatient Neurosurgical Center. St. Thomas Hospital also reported that methylprednisolone acetate used in the ESIs was obtained from NECC.

102. On September 20, 2012, Saint Thomas Outpatient Neurosurgical Center closed voluntarily, sequestered its supplies, and ordered new supplies from other distributors.

103. According to the CDC, fungal meningitis occurs when the protective membranes covering the brain and spinal cord are infected with a fungus. Fungal meningitis is rare and usually caused by the spread of a fungus through blood to the spinal cord. Fungal meningitis is not an infectious disease transmitted from person to person via normal contact.

104. According to the CDC, symptoms of meningitis include the following: new or worsening headache; fever; sensitivity to light; stiff neck; new weakness or numbness in any part of the body; slurred speech; and increased pain, redness, or swelling at the injection site. Death may result from meningitis.

105. According to the CDC, symptoms of fungal meningitis are similar to symptoms of other forms of meningitis; however, they often appear more gradually and can be very mild at first. In addition to typical meningitis symptoms, like headache, fever, nausea, and stiffness of the neck, people with fungal meningitis may also experience confusion, dizziness, and discomfort from bright lights. Patients might just have one or two of these symptoms.



**Injections Given to Decedent Dallas Ray Nealon**

106. Decedent Dallas Ray Nealon received MPA injections at Specialty Surgery Center on August 29, 2012 and September 26, 2012, and that compounded drug came from a lot of contaminated MPA that was subsequently recalled by NECC. After the on August 29, 2012 and September 26, 2012, injections, the Decedent Dallas Ray Nealon began experiencing altered mental status, urinary retention and subacute paraplegia, signs and symptoms consistent with his having contracted fungal meningitis. Decedent Dallas Ray Nealon's injections of MPA caused him to suffer fungal meningitis and severe complications related thereto, which eventually caused the wrongful death of Dallas Ray Nealon on December 9, 2012.

107. Plaintiff's Decedent Dallas Ray Nealon did not discover until after September 18, 2012, when it was eventually made public that the fungal meningitis outbreak in this country was linked to contaminated injectable steroid drug products that were supplied by NECC to various medical facilities, that the Defendant Specialty Surgery Center, PLLC had caused the Decedent Dallas Ray Nealon to receive contaminated injectable steroid drug products, and nor could the Decedent have reasonably discovered this had occurred, until after September 18, 2012.

**CAUSES OF ACTION - COUNT I NEGLIGENCE  
(Against NECC Related Defendants)**

108. As the designer, tester, compounder, seller, marketer and/or distributor of consumer products, the NECC Related Defendants owed a duty to the Plaintiff's Decedent Dallas Ray Nealon to comply with existing standards of care, and to exercise due care, in providing a safe and quality product to the Decedent Dallas Ray Nealon.

109. Specifically, but without limitation:

- a. Ameridose, MSM/MSMSW, GDC, Barry Cadden, Gregory Conigliaro, Lisa Cadden, Douglas Conigliaro, Carla Conigliaro, and Glenn Chin owed the Plaintiff a duty to provide methylprednisolone acetate that was safe and free of contamination.
- b. ARL owed the Plaintiff a duty to properly conduct tests to insure that the methylprednisolone acetate was safe and free of contamination.
- c. NECC Related Defendants sold steroids in bulk Specialty Surgery Center, but they were not authorized to compound and to sell MPA in bulk to Specialty Surgery Center, they were only allowed to fill individual prescriptions for individual patients written by appropriately licensed healthcare providers.

110. Defendants breached those duties, and were otherwise negligent in their compounding, sale, testing, marketing, and distribution of the recalled steroid medication, which was administered to the Plaintiff's Decedent Dallas Ray Nealon. The Defendants failed to exercise due care in accordance with the standard of care and skill required of, and ordinarily exercised by, a designer, compounder, tester, seller, marketer, and distributor of steroid medications, as licensed to do so by the Commonwealth of Massachusetts. The Defendants, by and through their supervisors, staff and agents engaged in designing, compounding, storing, testing, selling, marketing and distributing MPA in a negligent manner.

111. Defendants further breached those duties by failing to hold the components of the recalled medications; by failing to properly design, compound, test and distribute MPA so that it would not be contaminated with fungus; by failing to properly maintain its facilities where it compounded its medications in a clean, sanitary manner; by failing to oversee the security and quality control of its compounding and distribution facilities; and by allowing contaminated and unsafe compounded medications to reach the stream of commerce for use by the Decedent Dallas Ray Nealon.

112. Ameridose, MSM/MSMSW, GDC, ARL, Barry Cadden, Gregory Conigliaro, Lisa Cadden, Douglas Conigliaro, Carla Conigliaro and Glenn Chin breached the duties owed to the Plaintiff by failing to use reasonable care in designing, compounding, testing, marketing, distributing and/or selling methylprednisolone acetate.

113. The negligence of Ameridose, MSM/MSMSW, GDC, ARL, Barry Cadden, Gregory Conigliaro, Lisa Cadden, Douglas Conigliaro, Carla Conigliaro, and Glenn Chin was a proximate cause of the Decedent Dallas Ray Nealon's injuries and caused him to suffer fungal meningitis and severe complications related thereto, which eventually proximately caused the wrongful death of Dallas Ray Nealon on December 9, 2012, thereby resulting in the Plaintiff's claims for damages.

114. Plaintiff's Decedent Dallas Ray Nealon was exposed to fungal meningitis through NECC's contaminated steroid that was injected into his at Specialty Surgery Center on August 29, 2012, and September 26, 2012.

**COUNT II - NEGLIGENCE PER SE  
(Against all NECC Related Defendants except ARL)**

115. Ameridose, MSM/MSMSW, GDC, Barry Cadden, Gregory Conigliaro, Lisa Cadden, Douglas Conigliaro, Carla Conigliaro, and Glenn Chin owed the Plaintiff a duty to maintain the premises of the pharmacy "in a clean and sanitary manner[,]" 247 CMR 6.02(1), and free from contamination.

116. Ameridose, MSM/MSMSW, GDC, Barry Cadden, Gregory Conigliaro, Lisa Cadden, Douglas Conigliaro, Carla Conigliaro and Glenn Chin breached the duties owed to the Plaintiff's Decedent Dallas Ray Nealon by failing to use reasonable care in maintaining the premises of the pharmacy "in a clean and sanitary manner[,]" 247 CMR 6.02(1), and free from contamination.

117. Defendants also violated Massachusetts' laws and its pharmacy licensing obligations.

118. The aforementioned actions by Ameridose, MSM/MSMSW, GDC, Barry Cadden, Gregory Conigliaro, Lisa Cadden, Douglas Conigliaro, Carla Conigliaro, and Glenn Chin were a proximate cause of Plaintiff Decedent Dallas Ray Nealon's injuries and the Plaintiff's damages.

**COUNT III - NEGLIGENT SUPERVISION (Against NECC Related Defendants)**

119. Defendants Ameridose, MSM/MSMSW, GDC, ARL, Barry Cadden, Gregory Conigliaro, Lisa Cadden, Douglas Conigliaro, Carla Conigliaro, and Glenn Chin had an obligation and duty to exercise due care, and comply with the then existing standard of care, to investigate and hire professional and competent employees to create, test, package, market, and distribute the compounded medications and to maintain the facility and its premises, and to make sure the compounded drugs did not create any harm or risk to the Plaintiff and others who received the compounded medication.

120. In breach of those duties, Defendants failed to exercise due care and failed to supervise their employee(s) or agent(s), who were at all times working within the scope of their employment and authority. Specifically, and without limitation:

- a. The Defendants failed to monitor and test the steroid medication and were otherwise negligent in supervision of their employees.
- b. Defendants also failed to monitor and supervise the testing of the compounded medications.
- c. The Defendants were negligent in hiring, training, and supervising their employees.

121. The Defendants knew, or should have known, that their employee(s) or agent(s) did not follow proper procedures and knew or should have known of the risks created by failing to do so.

122. As a direct and proximate cause of the breach of those duties, the Defendants permitted the steroid to become contaminated and distributed to patients including the Decedent Dallas Ray Nealon.

123. The aforementioned actions by Ameridose, MSM/MSMSW, GDC, ARL, Barry Cadden, Gregory Conigliaro, Lisa Cadden, Douglas Conigliaro, Carla Conigliaro, and Glenn Chin were a proximate cause of the Decedent Dallas Ray Nealon's injuries and caused him to suffer fungal meningitis and severe complications related thereto, which eventually proximately caused the wrongful death of Dallas Ray Nealon on December 9, 2012, thereby resulting in the Plaintiff's claims for damages.

**COUNT IV - PUBLIC NUISANCE**  
**(Against Barry Cadden, Gregory Conigliaro and GDC)**

124. At all relevant times, Barry Cadden, Gregory Conigliaro, and/or GDC were in control of the property and improvements at 697 Waverly Street, Framingham, Massachusetts.

125. Barry Cadden, Gregory Conigliaro, and GDC owed a duty to maintain the property and improvements at 697 Waverly Street, Framingham, Massachusetts, in a condition that was free from contamination.

126. Barry Cadden, Gregory Conigliaro, and GDC failed to exercise reasonable care in maintaining the property and improvements at 697 Waverly Street, Framingham, Massachusetts.

127. The failure by Barry Cadden, Gregory Conigliaro, and GDC to maintain the property and improvements at 697 Waverly Street, Framingham, Massachusetts, was a proximate cause of the multi state epidemic of fungal meningitis and infections caused by the contaminated methylprednisolone acetate.

128. Barry Cadden, Gregory Conigliaro, and GDC unreasonably and significantly interfered with the public health and the public safety.

129. Barry Cadden, Gregory Conigliaro, and GDC unreasonably and significantly interfered with the public right expressed in 247 CMR 6.02(1).

130. The public nuisance created by Barry Cadden, Gregory Conigliaro, and GDC was a proximate cause of the Decedent Dallas Ray Nealon's injuries and caused him to suffer fungal meningitis and severe complications related thereto, which eventually proximately caused the wrongful death of Dallas Ray Nealon on December 9, 2012, thereby resulting in the Plaintiff's claims for damages.

**COUNT V - PRODUCT LIABILITY CLAIMS  
(Against Specialty Surgery Center)**

131. The MPA injected into Decedent Dallas Ray Nealon's spine was compounded by NECC.

132. On December 21, 2012, NECC filed a voluntary petition pursuant to Chapter 11 of Title 11 of the United States Bankruptcy Code in the United States Bankruptcy Court for the District of Massachusetts, In re: New England Compounding Pharmacy, Inc., case no. 12-19882HJB.

133. Pursuant to 11 U.S.C. § 362(a)(I) certain actions against NECC are stayed following its bankruptcy petition.

134. Plaintiffs could have commenced an action in this court seeking to recover on a claim and seeking a judgment against NECC before December 21, 2012.

135. Plaintiffs' claims that arose before NECC's petition in bankruptcy are subject to the automatic stay provisions of 11 U.S.C. § 362(a)(1).

136. NECC has ceased operations.

137. NECC is unable to pay its debts as they fall due.

138. NECC is unable to pay its debts in the ordinary course of its business.

139. NECC's liabilities exceed its assets.

140. NECC is insolvent.

141. On July 24, 2013, The United States Bankruptcy Court for the District of Massachusetts in In re: New England Compounding Pharmacy, Inc., Case no. 12-19882-HJB, ordered that with respect to certain claims, including those asserted by Plaintiffs in this lawsuit, NECC is presently insolvent and has been insolvent at all times since the petition date.

142. Specialty Surgery Center procured the MPA injected into Decedent Dallas Ray Nealon's spine from NECC.

143. NECC's product was defective and unreasonably dangerous when it left NECC's control because it was contaminated with infectious and potentially lethal pathogens, and it was in substantially the same condition at the time that Specialty Surgery Center injected it into Decedent Dallas Ray Nealon's spine.

144. Specialty Surgery Center charged the Decedent Dallas Ray Nealon for epidural steroid injections administered to Decedent Dallas Ray Nealon.

145. Specialty Surgery Center acted as a seller or distributor of MPA compounded by NECC when it sold and administered epidural steroid injections to patients, including Decedent Dallas Ray Nealon.

146. Specialty Surgery Center was engaged in the business of selling MPA compounded by NECC.

147. Accordingly, Specialty Surgery Center is a "seller" as defined by T.C.A. § 29-28-102(7).

148. T.C.A. § 29-28-106(4) authorizes the Plaintiff to prosecute product liability claims against Specialty Surgery Center as the seller of the MPA injected into Decedent Dallas Ray Nealon's spine because the compounder of the product, NECC, cannot be served with process in this state.

149. T.C.A. § 29-28-106(5) authorizes the Plaintiff to prosecute product liability claims against Specialty Surgery Center as the seller of the MPA injected into Decedent Dallas Ray Nealon's spine because the compounder of the product, NECC, has been judicially declared insolvent.

150. The MPA that Specialty Surgery Center injected into Decedent Dallas Ray Nealon's spine was unreasonably dangerous and defective at the time it left their control because it was contaminated with infectious and lethal pathogens.

151. Specifically, the MPA was in a defective condition and unreasonably dangerous at all relevant times because it was unsafe for normal or anticipated handling as defined by T.C.A. § 29-28-102(2).

152. The MPA sold and distributed by Specialty Surgery Center was neither merchantable nor fit for the purpose for which it was produced and sold. Accordingly, Specialty Surgery Center breached their

warranties, both express and implied, as stated in T.C.A. §§ 47-2-313, 47-2-314, and 47-2-315, including their warranty of fitness for a particular purpose.

153. Specialty Surgery Center is strictly liable for the injuries and losses caused by the unreasonably dangerous and defective steroids injected into Decedent Dallas Ray Nealon's spine.

#### **CAUSATION**

154. Plaintiff hereby incorporates by reference the allegations and causes of action pled in the preceding Paragraphs of this Complaint, as to the liability of the Defendants. The foregoing negligent acts and omissions and reckless misconduct committed by the Defendants did singularly and/or collectively, directly and proximately cause the injuries suffered by the Plaintiff's Decedent Dallas Ray Nealon, and caused him to suffer fungal meningitis and severe complications related thereto, which eventually caused the wrongful death of Dallas Ray Nealon on December 9, 2012, thereby resulting in the Plaintiff's damages, as set forth herein below.

#### **SPECIAL & GENERAL DAMAGES**

155. All of the above paragraphs are incorporated herein by reference. Plaintiff avers that as a direct and proximate result of these negligent acts and omissions and reckless misconduct committed by the Defendants, the Plaintiff's Decedent Dallas Ray Nealon became very ill and he suffered horribly with altered mental status, urinary retention, subacute paraplegia and other severe complications related to his fungal meningitis contamination, which eventually caused the wrongful death of Dallas Ray Nealon on December 9, 2012.

156. Plaintiff has incurred and claims the following damages:

- a. The pecuniary value of the life of Dallas Ray Nealon;
- b. Pain and suffering;
- c. Mental anguish;
- d. Funeral and medical expenses, and;
- e. Consortium losses including, but not limited to, the loss of companionship, comfort, society, solace and love of Dallas Ray Nealon as a direct result of his wrongful death.



### **PUNITIVE DAMAGES**

157. Plaintiff specifically avers that punitive damages are appropriate in this case and allege that the acts and omissions of the Defendants, as described hereinabove, constituted reckless, willful and wanton disregard for the Decedent Dallas Ray Nealon's health, safety and survival. The Defendants, through their officers, managers, employees agents or servants, have no reasonable excuse for their conduct, and were well aware of the risk of severe injury and potential death to the Decedent Dallas Ray Nealon and to other patients, due to the Defendants' failures as itemized hereinabove, but the Defendants were reckless, willful and wanton in their disregard of those known risks. Accordingly, Defendants should be compelled to pay damages in order to punish their wrongful conduct and to deter similar wrongful conduct in the future.

### **CAPS FOUND IN T.C.A. § 29-39-102 & § 29-39-104 ARE UNCONSTITUTIONAL AND VOID *AB INITIO***

158. Plaintiff seeks a judgment pursuant to the Declaratory Judgment Act, 28 U.S.C. § 2201, declaring that the caps on personal injury and punitive damages set forth in T.C.A. § 29-39-102 and T.C.A. § 29-39-104 are an unconstitutional deprivation of the right to trial by jury set forth in Article I, Section 6, of the Constitution of the State of Tennessee, which provides that the right of trial by jury shall remain inviolate, and violate the provisions of Article XI, Section 16, of the Constitution of the State of Tennessee, which absolutely precludes the Legislature from exercising any legislative power to remove or restrict the right of juries in civil cases to determine damages.

159. On October 1, 2011, the Tennessee Civil Justice Act went into effect, enacting "caps" in all Tennessee personal injury cases for non-economic damages and punitive damages. T.C.A. § 29-39-102; Tenn. Code Ann. § 29-39-104. Under that Act, Plaintiffs' non-economic damages are purportedly capped at \$750,000.00, and their ability to recover punitive damages is capped at twice the compensatory damages, up to a maximum of \$500,000.00.



160. T.C.A. § 29-39-102 and T.C.A. § 29-39-104 are unconstitutional deprivations of Plaintiff's constitutionally protected right to trial by jury. Those provisions violate Article I, Section 6, of the Constitution of the State of Tennessee, which provides that the right of trial by jury shall remain inviolate. In addition, the subject statutory caps violate Article I, Section 17, of the Tennessee Constitution, which states that all courts shall be open, and every man shall have a remedy for injury done by due course of law and without denial or delay. The subject statutory caps usurp the powers of the Judicial Branch in violation of Article II, Sections 1 & 2 of the Tennessee Constitution. In addition, the statutory caps violate Article XI, Section 16, of the Tennessee Constitution which provides that the rights of citizens articulated in Tennessee's Bill of Rights "shall never be violated on any pretense whatever... and shall forever remain inviolate."

161. Therefore, Plaintiff requests a declaration that the statutory caps are unconstitutional, void *ab initio*, and of no force and effect.

162. Pursuant to T.C.A. § 29-14-107, a copy of this Complaint is being served on the Attorney General of the State of Tennessee, notifying the State of Tennessee Attorney General that the Plaintiff is challenging the constitutionality of T.C.A. § 29-39-102 and T.C.A. § 29-39-104.

#### **PRAYER FOR RELIEF**

**WHEREFORE**, Plaintiff sues the Defendants for the following relief:

- a. A judgment to the plaintiff for compensatory damages in excess of \$75,000;
- b. A judgment for punitive damages in an amount to be determined by the trier of fact;
- c. For accrued post-judgment interest paid at the legal rates;
- d. For the costs of this cause, including reasonable expenses; and
- e. For any and all further relief and damages as the Court may deem just and proper and to which he may be entitled.

**PLAINTIFF DEMANDS A JURY OF TWELVE PERSONS TO TRY THESE ISSUES WHEN JOINED.**

Respectfully submitted,

MCMAHAN LAW FIRM

By: 

James R. Kennamer, TN BPR No. 16172  
P.O. Box 11107

Chattanooga, TN 37401-2107

Telephone: (423) 265-1100

Facsimile: (423) 756-8120

E-Mail: [jaykennamer@mcmahanlawfirm.com](mailto:jaykennamer@mcmahanlawfirm.com)

**Attorneys for the Plaintiff**

IN THE PROBATE AND FAMILY COURT OF CUMBERLAND COUNTY, TENNESSEE

IN THE MATTER OF THE ESTATE OF  
DALLAS RAY NEALON, DECEASED.

No. 2013-PF-3466

\*  
\*  
\*  
\*  
\*

**ORDER APPOINTING PERSONAL REPRESENTATIVE FOR CAUSE OF ACTION ONLY**

On Aug 1, 2013, Darwin L. Nealon presented to the Court a petition to have himself appointed Administrator *ad litem* of the Estate of Dallas Ray Nealon, deceased, and R. Lew Belvin, III, Attorney for the petitioner, moved the Court to appoint Darwin L. Nealon as Administrator *ad litem* of said estate for the limited purpose of a cause of action only.

It appearing to the Court that said Deceased Dallas Ray Nealon died on December 9, 2012, and the decedent's usual place of residence at the time of death was in Cumberland County, Tennessee.

**IT IS ORDERED,**

The estate be opened for cause of action only, no further reports are required by the Probate Court in this cause, and no Bond is required by the Probate Court, the costs having been paid in full by Petitioner.

ENTER Aug 1, 2013.

APPROVED: [Signature]

R. Lew Belvin, III, BPR# 028325  
MCMAHAN LAW FIRM  
P.O. Box 11107  
Chattanooga, TN 37401-2107  
(423) 265-1100  
Attorney for Petitioner, Darwin L. Nealon

[Signature]  
THE HONORABLE LARRY M. WARNER, JUDGE

FILED  
Date 8-1-13 3:40 AM  
Entered 8-1-13  
SUE TOLLETT, CLERK & MASTER  
Cumberland County, Crossville, TN  
BY [Signature]

The undersigned hereby certifies that a copy of this Order has been provided to the counsel for the Petitioner in this case.

This 1st day of August, 2013.

SUE TOLLETT, CLERK & MASTER

By: [Signature]  
Deputy Probate Clerk

STATE OF TENNESSEE, COUNTY OF CUMBERLAND  
I, THE UNDERSIGNED, CLERK & MASTER OF SAID  
COUNTY AND STATE, DO HEREBY CERTIFY THAT  
THIS IS A TRUE AND CORRECT COPY OF THE  
ORIGINAL OF THIS INSTRUMENT.  
THIS 1st DAY OF August, 2013  
[Signature]  
CLERK & MASTER

**EXHIBIT A**

**UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF MASSACHUSETTS**

**DARWIN L. NEALON, AS SON, NEXT OF KIN TO  
AND AS THE ADMINISTRATOR OF THE ESTATE  
OF DALLAS RAY NEALON, DECEASED**

**Plaintiff,**

**v.**

**AMERIDOSE, LLC, MEDICAL SALES  
MANAGEMENT, INC., MEDICAL SALES  
MANAGEMENT SW, INC., GDC  
PROPERTIES MANAGEMENT, LLC,  
ARL BIO PHARMA, INC. d/b/a  
ANALYTICAL RESEARCH LABORATORIES,  
BARRY J. CADDEN, GREGORY CONIGLIARO,  
LISA CONIGLIARO CADDEN, DOUGLAS  
CONIGLIARO, CARLA CONIGLIARO,  
GLENN A. CHIN, SPECIALTY SURGERY  
CENTER, LLC and UNIFIRST  
CORPORATION A/D/B/A UNICLEAN  
CLEANROOM SERVICES**

**Defendants.**

**CIVIL ACTION NO. 1:13-cv-12491-FDS**

**MDL No.2419**

**Master Docket No.1:13-md-2419-FDS**

**Honorable F. Dennis Saylor**

**DEMAND FOR JURY TRIAL**

**SHORT FORM COMPLAINT  
AGAINST UNAFFILIATED DEFENDANTS**

Plaintiff, Darwin L. Nealon, as Son, Next of Kin to and as Administrator of the Estate of Dallas Ray Nealon, Deceased, for his cause of action against the Defendants, alleges as follows:

**FIRST COUNT**

1. Pursuant to MDL Order No.7, entered in In Re: New England Compounding Pharmacy, Inc. Products liability Litigation, Master Docket No. 1:13-md-2419-FDS, the undersigned counsel hereby submit this Short Form Complaint and Jury Demand against Defendants, and adopt and incorporate by reference the allegations in Plaintiffs' Master Complaint, with attachments, and any and all amendments thereto.

2. The Plaintiff Darwin L. Nealon is a citizen and resident of Ohio and he resides at 1260 Crosscreek Drive, Apt. 71, Brunswick, Ohio, 44212, in Medina County, Ohio. At the time of his death, Plaintiff's Decedent Dallas Ray Nealon was a citizen and resident of Tennessee and he resided at 90 Adelaide Street, Crossville,

- ☐ COUNT IV: VIOLATION OF CONSUMER PROTECTION STATUTES (Against Clinic Related Defendant)

Plaintiff alleges violation of the following consumer protection statutes: T.C.A. § 29-28-102(2)&(7); T.C.A. § 29-28-106(4)&(5); T.C.A. §§ 47-2-313, 47-2-314, and 47-2-315; Note that N.J.S.A. 56:8-1 *et seq.* was inadvertently omitted from the Master Complaint]

- ☐ COUNT VI: VIOLATION OF M.G.L.C. 93A (Against UniFirst)
- ☐ COUNT VII: BATTERY (Against Clinic Related Defendant)
- ☒ COUNT VIII: FAILURE TO WARN (Against Clinic Related Defendant)
- ☒ COUNT IX: TENNESSEE PRODUCT LIABILITY CLAIMS (Against Clinic Related Defendant)
- ☒ COUNT X: AGENCY (Against Clinic Related Defendant)
- ☒ COUNT XI: CIVIL CONSPIRACY (Against Clinic Related Defendant)
- ☒ COUNT XII: WRONGFUL DEATH PUNITIVE DAMAGES (Against UniFirst and Clinic Related Defendant)
- ☒ COUNT XIII: LOSS OF CONSORTIUM (Against UniFirst and Clinic Related Defendant)
- ☒ COUNT XIV: PUNITIVE DAMAGES (Against UniFirst and Clinic Related Defendant)

9. Plaintiff has sent or served the pre-suit notice or demand requirements necessary to bring the claims set forth below, as required under M.G.L.C. 93A. Plaintiff does not now assert but will seek leave to amend to assert the following claims promptly after the time period for giving notice has expired: VIOLATION OF M.G.L.C. 93A (as set forth in Count VI of the Master Complaint).

10. Plaintiff avers that as a direct and proximate result of these negligent acts and omissions and reckless misconduct committed by the Defendants, the Plaintiff's Decedent Dallas Ray Nealon became very ill and he suffered horribly with altered mental status, urinary retention, subacute paraplegia and other severe complications related to his fungal meningitis contamination, which eventually caused the wrongful death of Dallas Ray Nealon on December 9, 2012.

11. Plaintiff Darwin L. Nealon and his Decedent Dallas Ray Nealon suffered the following damages as a result of the administration of NECC's drug(s): the pecuniary value of the life of Dallas Ray Nealon; Pain and suffering; Mental anguish; Funeral and medical expenses, and Consortium losses including, but not limited to, the loss of companionship, comfort, society, solace and love of Dallas Ray Nealon as a direct result of his wrongful death.

12. Plaintiff reserves the right to amend this Complaint to add allegations and claims against individuals or entities currently omitted (in light of the Court's order permitting a Master Complaint naming defendants affiliated with NECC and currently participating in mediation by December 20, 2013) and to add or amend allegations against Defendants named herein based, in part, on further discovery.

WHEREFORE, Plaintiff demands Judgment against Defendants awarding compensatory damages, punitive damages, attorneys' fees, interest, costs of suit, and such further relief as the Court deems equitable and just. Plaintiff prays for damages in an amount exceeding \$75,000.00 as set forth in Plaintiff's Original Complaint.

#### **SECOND COUNT**

13. Plaintiff re-alleges and incorporate by reference each of the foregoing paragraphs as if set forth at length herein.

14. Plaintiff asserts the following additional Causes of Action against Defendants:  
Plaintiff incorporates all allegations and counts contained in Plaintiff's Original Complaint found at Docket No.1, together with all attachments thereto, [see docket nos. 1-1 through 1-5] in the litigation styled Darwin L. Nealon, as Son, Next of Kin to and as Administrator of the Estate of Dallas Ray Nealon, Deceased, v. Ameridose LLC. et al.; United States District Court, District of Massachusetts, 1:13-cv-12491, (MDL No. 1:13-md-2419-FDS) together with all prayers for relief stated therein.

15. Plaintiff suffered injuries as set forth in Paragraph 10 herein.

16. Plaintiff suffered damages as set forth in Paragraph 11 herein.

WHEREFORE, Plaintiff demands Judgment against Defendants awarding compensatory damages, punitive damages, attorneys' fees, interest, costs of suit, and such further relief as the Court deems equitable and just.

**JURY DEMAND**

Plaintiff hereby demands a trial by jury.

Respectfully submitted,

MCMAHAN LAW FIRM

**By: /s/ James R. Kennamer**

James R. Kennamer, TN BPR No. 16172

P.O. Box 11107

Chattanooga, TN 37401-2107

Telephone: (423) 265-1100

Facsimile: (423) 756-8120

E-Mail: jaykennamer@mcmahanlawfirm.com

**Attorneys for the Plaintiff**

Date: **December 19, 2013**



IN THE UNITED STATES DISTRICT COURT  
MIDDLE DISTRICT OF TENNESSEE

JOCELYN KAE NORRIS,

Plaintiff,

v.

AMERIDOSE, LLC, MEDICAL SALES  
MANAGEMENT, INC., MEDICAL SALES  
MANAGEMENT SW, INC., GDC  
PROPERTIES MANAGEMENT, LLC, ARL  
BIO PHARMA, INC. D/B/A ANALYTICAL  
RESEARCH LABORATORIES, BARRY J.  
CADDEN, GREGORY CONIGLIARO, LISA  
CONIGLIARO CADDEN, DOUGLAS  
CONIGLIARO, CARLA CONIGLIARO,  
GLENN A. CHIN, and SPECIALTY  
SURGERY CENTER, PLLC d/b/a  
SPECIALTY SURGERY CENTER,

Defendants.

Case No. \_\_\_\_\_  
JURY DEMAND

COMPLAINT

The Plaintiff, Jocelyn Kae Norris, for her cause of action against the Defendants respectfully states to the Court as follows:

INTRODUCTION

1. This lawsuit arises as a result of a widespread outbreak of fungal meningitis over the past year that has affected people in at least 20 states and caused over 60 deaths. Over 700 people have been diagnosed with meningitis.

2. The United States Food and Drug Administration ("FDA") and the Centers for Disease Control ("CDC") have identified fungus present in several separate lots of preservative-free injectable steroids, specifically, methylprednisolone acetate (sometimes referred to as

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“MPA”), that was compounded and distributed by New England Compounding Pharmacy, Inc. d/b/a New England Compounding Center (“NECC”) as the cause of the fungal meningitis outbreak and the resulting injuries and deaths.

3. Multiple vials of steroids compounded at NECC have been recalled but the recall was too late for Plaintiff Jocelyn Kae Norris (“Ms. Norris”) and for many others who have suffered serious and at times catastrophic injuries.

4. Upon information and belief, between June and September 2012, Specialty Surgery Center, PLLC d/b/a Specialty Surgery Center (“Specialty Surgery”) purchased hundreds or thousands of vials of MPA from NECC and then sold and administered the MPA to patients including Ms. Norris.

5. On July 18 and September 25, 2012, Ms. Norris received epidural steroid injections (“ESI”) at Specialty Surgery. During those procedures, Ms. Norris was injected with MPA.

6. Ms. Norris’ July 18 and September 25, 2012 MPA injections came from one or more contaminated lots of MPA that were purchased from NECC. The contaminated lots were subsequently recalled by NECC.

7. Ms. Norris’ July 18 and/or September 25, 2012 injections of MPA caused her personal injury.

#### PARTIES

8. Ms. Norris is a citizen and resident of the State of Tennessee and resides at 287 Kingsdown Drive, Fairfield Glade, Cumberland County, Tennessee 38558.

9. Defendant Ameridose, LLC (“Ameridose”) is a Massachusetts limited liability company organized and domesticated under the laws of the Commonwealth of Massachusetts

with a principal place of business at 205 Flanders Road, Westborough, Massachusetts 01581. The managers of Ameridose are Gregory Conigliaro and Barry Cadden. Ameridose's registered agent is Gregory Conigliaro.

10. Defendant Medical Sales Management, Inc. ("MSM") is a Massachusetts corporation organized and domesticated under the laws of the Commonwealth of Massachusetts with its principal place of business at 697 Waverly Street, Framingham, Massachusetts 01702. Douglas Conigliaro is the President and a Director of MSM. Barry Cadden is the Treasurer and a Director of MSM. Gregory Conigliaro is the Secretary and a Director of MSM. MSM's registered agent is Gregory Conigliaro.

11. Defendant Medical Sales Management SW, Inc. ("MSMSW") is a Massachusetts corporation organized and domesticated under the laws of the Commonwealth of Massachusetts with its principal place of business at 697 Waverly Street, Framingham, Massachusetts 01702. Douglas Conigliaro is the President and a Director, Barry Cadden is the Treasurer and a Director, Gregory Conigliaro is the Secretary and a Director and Lisa Conigliaro. MSMSW's registered agent is Gregory Conigliaro.

12. Defendant GDC Properties Management, LLC ("GDC"), is a Massachusetts limited liability company organized and domesticated under the laws of the Commonwealth of Massachusetts with its principal place of business at 701 Waverly Street, Framingham, Massachusetts 01702. GDC's manager and registered agent is Gregory Conigliaro.

13. Defendant ARL Bio Pharma, Inc. d/b/a Analytical Research Laboratories ("ARL") is an Oklahoma corporation organized and domesticated under the laws of the State of Oklahoma with a principal place of business at 840 Research Parkway, Suite 546,

Oklahoma City, Oklahoma 73104. Thomas C. Kupiec is the Chief Executive Officer and registered agent of ARL.

14. Defendant Barry J. Cadden (“Barry Cadden”) is an individual residing at 13 Manchester Drive, Wrentham, Massachusetts 02093 and a citizen and resident of the Commonwealth of Massachusetts. Barry Cadden is the President of NECC, which is a Massachusetts corporation. At least until October 2012, Barry Cadden was NECC’s licensed Pharmacist Manager of Record. Barry Cadden is a founder and Manager of Ameridose and was involved in Ameridose’s day to day operations. Barry Cadden is the Treasurer and a Director of MSM and MSMSW.

15. Defendant Gregory Conigliaro (“Gregory Conigliaro”) is an individual residing at 1 Mountain View Drive, Framingham, Massachusetts 01701 and a citizen and resident of the Commonwealth of Massachusetts. Gregory Conigliaro is a principal owner and the general manager of NECC, as well as NECC’s Treasurer, Secretary, Vice President, registered agent, and one of its Directors. Gregory Conigliaro provided financial advice, oversaw day to day operations, and regularly appeared in the NECC facility. Gregory Conigliaro is the founder and a Manager of Ameridose and involved in Ameridose’s day to day operations. Gregory Conigliaro is Secretary and a Director of MSM and MSMSW.

16. Defendant Lisa Conigliaro Cadden (“Lisa Cadden”) is an individual residing at 13 Manchester Drive, Wrentham, Massachusetts 02093 and a citizen and resident of the Commonwealth of Massachusetts. Lisa Cadden is a board member, Director and, at least until October 2012, a pharmacist at NECC. Lisa Cadden, upon information and belief, compounded drugs and was involved in the day to day operations of NECC.



17. Defendant Douglas Conigliaro (“Douglas Conigliaro”) is an individual residing at 15 Hale Drive, Dedham, Massachusetts 02026 and a citizen and resident of the Commonwealth of Massachusetts. Douglas Conigliaro is the President and a Director of MSM and MSMSW. Douglas Conigliaro, upon information and belief, is involved in the day to day operations of NECC, Ameridose, MSM, and MSMSW.

18. Defendant Carla Conigliaro (“Carla Conigliaro”) is an individual residing at 15 Hale Drive, Dedham, Massachusetts 02026, and a citizen and resident of the Commonwealth of Massachusetts and is a Director of NECC.

19. Defendant Glenn A. Chin (“Glenn Chin”) is an individual residing at 173 Mechanic Street, Canton, Massachusetts 02021 and a citizen and resident of the Commonwealth of Massachusetts. At least until October 2012, Glenn Chin was a pharmacist at NECC. Glenn Chin, upon information and belief, compounded drugs at NECC.

20. Defendant Specialty Surgery Center, PLLC d/b/a Specialty Surgery Center (“Specialty Surgery”) is an active for profit limited liability Company organized and domesticated under the laws of the State of Tennessee. Specialty Surgery’s principal place of business is located at 116 Brown Avenue, Crossville, TN 38555-7703. Specialty Surgery’s registered agent for service of process is Donathan M. Ivey, Brown Avenue, Crossville, TN 38555-7703. At all times while providing and selling drug products to Ms. Norris at Specialty Surgery, the physicians, nurses, staff, and other personnel were agents, apparent agents, employees or representatives of Specialty Surgery and were acting within the course and scope of their employment, agency, or apparent agency with Specialty Surgery. Accordingly, Specialty Surgery, under the doctrine of *respondeat superior*, is vicariously liable for any negligent acts

and omissions of their employees, agents, or representatives committed in the course and scope of their employment or agency while providing and selling drug products to Ms. Norris.

21. The individuals and entities described in paragraphs 9-19 are sometimes collectively referred to as the “NECC Related Defendants.”

#### JURISDICTION AND VENUE

22. This Court has subject matter jurisdiction over the parties pursuant to 28 U.S.C. § 1331 because this action arises under the laws or treaties of the United States. Specifically this Court has jurisdiction pursuant to 28 U.S.C. § 1334(b) because as described herein this case is related to a case under title 11.

23. On December 21, 2012, NECC filed a petition for Bankruptcy protection under Chapter 11 of the Bankruptcy Code: In re New England Compounding Pharmacy, Inc., Debtor, United States Bankruptcy Court for the District of Massachusetts, Case no. 12:19882-HJB. A United States Trustee was subsequently appointed to administer the Bankruptcy Estate. The Bankruptcy Court has not yet established a deadline for the filing of claims against NECC’s bankruptcy estate In re New England Compounding Pharmacy, Inc.

24. According to NECC’s Bankruptcy Trustee, NECC has express contractual indemnification obligations including but not limited to Barry Cadden, Gregory Conigliaro, Lisa Cadden, Carla Conigliaro, Glenn Chin, GDC and MSM. Some if not all of the aforementioned individuals are insureds under NECC’s insurance policies. Adversarial cases seeking recovery of damages for the benefit of the bankruptcy estate and its unsecured creditors have been filed in NECC’s bankruptcy against each of the NECC Related Defendants.

25. This case is related to the NECC Bankruptcy because the outcome of the proceeding certainly could have some effect on the bankruptcy estate.

26. Lawsuits alleging death or injury based on contaminated MPA have been filed around the country. On February 12, 2013, the Judicial Panel on Multidistrict Litigation(MDL No. 2419) issued an order under 28 U.S.C. § 1407 transferring various federal-court proceedings to the United States District Court for the District of Massachusetts for coordinated or consolidated pretrial proceedings. The transferred actions are pending in the United States District Court for the District of Massachusetts in the Multidistrict Litigation action styled: IN RE: New England Compounding Pharmacy, Inc. Products Liability Litigation, United States District Court, District of Massachusetts, MDL No. 1:13-md-2419-FDS. The transferred cases, including one filed by Ms. Norris against NECC, have been assigned to the Honorable F. Dennis Saylor, United States District Judge, for pre-trial proceedings and coordination.

27. Upon information and belief, Specialty Surgery presently intends to seek, and will seek, relief from the stay in order to pursue contribution or indemnity claims against NECC for all or some portion of the damages sought by this Complaint. In addition or in the alternative, Specialty Surgery presently intends to file, and will file, claims in NECC's bankruptcy proceeding seeking indemnification or contribution for all or some portion of the damages sought by this Complaint.

28. By Order dated May 31, 2013, Judge Saylor, ruled that the New England Compounding Pharmacy, Inc. Multi District Litigation Court has subject-matter jurisdiction over any cases pending in federal court or state court against entities or individuals "affiliated" with NECC whether or not NECC is named as a defendant. Those NECC affiliated entities and



individuals referred to by Judge Saylor in his May 31, 2013 Order include the defendants described in paragraphs 9-19.

29. In addition, or in the alternative, this Court has subject-matter jurisdiction over all claims against Specialty Surgery pursuant to 28 U.S.C. § 1367 in that all claims are so related to claims in this action within the original jurisdiction of this Court that they form part of the same case or controversy under Article III of the United States Constitution.

30. Venue is proper and appropriate in the United States District Court for the Middle District of Tennessee pursuant to 28 U.S.C. § 1391(b)(2) in that all or a substantial part of the events and actions giving rise to the matters asserted in the Complaint occurred in Cumberland County, Tennessee.

31. At all times relevant the Defendants were engaged in the business of developing, compounding, marketing, distributing, promoting, selecting, purchasing and/or selling or administering either directly, or indirectly steroids in the State of Tennessee from which they derived significant and regular income.

32. Defendants are subject to the jurisdiction of this Court in that they are generally present in Tennessee, have transacted business within the State of Tennessee, and acting individually and/or through their agents and employees have committed tortious actions and omissions in Cumberland County, Tennessee that have proximately caused the injuries that are the subject of this lawsuit.

33. The NECC related Defendants are further subject to the jurisdiction of this Court as a result of contracting to supply goods and things in Tennessee, by conducting or soliciting business in Tennessee, by engaging in a persistent course of conduct in Tennessee, and by deriving substantial revenue from goods used or consumed or services rendered in Tennessee.

STATEMENT OF FACTS

Relevant background

34. NECC is an entity that has filed for bankruptcy and is protected by the automatic stay provisions of 11 U.S.C. § 362. Prior to NECC filing for bankruptcy, Ms. Norris filed suit against NECC in the Circuit Court for Cumberland County, Tennessee, a case which was removed and transferred to the United States District Court for the District of Massachusetts in the Multidistrict Litigation action styled: IN RE: New England Compounding Pharmacy, Inc. Products Liability Litigation, United States District Court, District of Massachusetts, MDL No. 1:13-md-2419-FDS.

35. NECC was a compounding pharmacy that compounded, distributed and/or sold drugs to purchasers throughout the United States, including Tennessee.

36. Upon information and belief, NECC was a privately-held company that was owned and controlled by Barry Cadden, Gregory Conigliaro, Douglas Conigliaro, Carla Conigliaro and Lisa Cadden.

37. Ameridose, GDC, MSM and MSMSW were affiliates of NECC at all relevant times.

38. At least until October 2012, Gregory Conigliaro was involved in co-managing day-to-day operations of NECC, MSM, MSMSW, Ameridose and GDC.

39. At least until October 2012, Lisa Cadden was a licensed pharmacist who, upon information and belief, compounded medications including MPA at NECC.

40. At least until October 2012, Glenn Chin was a licensed pharmacist who, upon information and belief, compounded medications including MPA at NECC.



41. At least until October 2012, Barry Cadden was a licensed pharmacist. In addition to being NECC's President, Barry Cadden was NECC's licensed Pharmacist Manager of Record. Upon information and belief, Barry Cadden compounded medications including MPA at NECC.

42. "Manager of Record or Pharmacist Manager of Record," as defined by 247 CMR 2.00, "means a pharmacist, currently registered by the [Massachusetts] Board [of Registration in Pharmacy] pursuant to 247 CMR 6.07, who is responsible for the operation of a pharmacy or pharmacy department in conformance with all laws and regulations pertinent to the practice of pharmacy and the distribution of drugs."

43. Ameridose, according to an application signed by Gregory Conigliaro and filed with the Massachusetts Board of Registration in Pharmacy on May 14, 2012, is a "distribution center to entities of common ownership – currently Ameridose and NECC, as well as other Properly Licensed Facilities in the future."

44. On information and belief and upon the direction of NECC's principals, on April 11, 2011, Ameridose employee Michelle Rivers requested certification for pharmacy technicians employed by NECC for use in an inspection of NECC's facilities by the Massachusetts Board of Registration in Pharmacy.

45. On or about August 24, 2012, Ameridose posted an employment opportunity for Registered Pharmacists to work for NECC in Framingham, Massachusetts. In the posting, potential applicants were told to contact [mlord@medicalesalesmgmt.com](mailto:mlord@medicalesalesmgmt.com). Upon information and belief, there were many other occasions where employees of Ameridose, MSM and/or MSMSW would perform services for NECC at the direction of NECC's principals.

46. Between 2006 and the present, Ameridose and NECC would often share a booth at conferences and conventions with a single banner listing both company names. During that

same time, Ameridose and NECC would hold an annual Christmas party for employees of both companies.

47. MSM and/or MSMSW printed materials for and marketed both NECC's and Ameridose's products, including MPA. One former employee of MSM and/or MSMSW has stated: "I didn't think there was any difference [between Ameridose and NECC]."

48. Through September 2012, both NECC and Ameridose used MSM and/or MSMSW for sales and marketing functions. NECC's privacy policy on its website referred to the "Ameridose Privacy Policy." In 2012, NECC salespersons recommended NECC's "sister company," Ameridose, for drug compounds that NECC did not have available.

49. MSM and/or MSMSW shared office space owned by GDC Properties with NECC in Framingham, Massachusetts.

50. Since it was formed as a limited liability company in 2006, Ameridose has been controlled by NECC.

51. Both Ameridose and NECC were controlled by Conigliaro and Cadden family members.

#### Claims Against the NECC Related Defendants

52. NECC has a well-known history of adverse events relating to its operation as a compounding pharmacy. According to the Majority Memorandum for the November 14, 2012 Oversight and Investigations Subcommittee Hearing, NECC has been the subject of multiple complaints to and investigations by the FDA and the Massachusetts Board of Registration in Pharmacy ("MBP") over the past decade often focusing on unsterile conditions at NECC's facilities. For example, the FDA issued a Warning Letter to NECC in 2006. The FDA letter details numerous problems at NECC including the sale of compounded drugs without patient-

specific prescriptions, compounding copies of commercially available drugs, selling misbranded compounded drugs, and problems with storage and sterility. That warning letter has been available to the public on the FDA's website for years.

53. Between January 2012 and August 2012, NECC's environmental monitoring program for its compounding facility yielded numerous microbiological isolates (bacteria and mold) within the Clean Room used for the production of methylprednisolone acetate. NECC, Barry Cadden, Gregory Conigliaro, Lisa Cadden, Douglas Conigliaro, Carla Conigliaro, Glenn Chin, Ameridose, MSM and/or MSMSW and GDC knew or should have known of these findings. NECC, Barry Cadden, Gregory Conigliaro, Lisa Cadden, Douglas Conigliaro, Carla Conigliaro, Glenn Chin, Ameridose, MSM and/or MSMSW and GDC failed to investigate those isolates and made no effort to identify those isolates. NECC, Barry Cadden, Gregory Conigliaro, Lisa Cadden, Douglas Conigliaro, Carla Conigliaro, Glenn Chin, Ameridose, MSM and/or MSMSW and GDC failed to perform any product assessments for the products made in the Clean Room where the isolates were found. NECC, Barry Cadden, Gregory Conigliaro, Lisa Cadden, Douglas Conigliaro, Carla Conigliaro, Glenn Chin, Ameridose, MSM and/or MSMSW and GDC failed to take any corrective actions with regards to the isolates that were found. Despite these findings, NECC continued to compound MPA, and Ameridose, MSM and/or MSMSW continued to distribute marketing materials to customers and potential customers touting the cleanliness of the NECC laboratories.

54. On September 26, 2012 in the wake of dozens of cases of fungal meningitis associated with NECC's injectable steroid MPA, state agents raided NECC's lab in a strip mall on Waverly Street in Framingham, Massachusetts.



55. NECC's few remaining employees were scrubbing the compounding areas with bleach. Despite this last-ditch effort, the "clean" rooms were filthy. A leaky boiler stood in a pool of stagnant, dirty water. The autoclaves used to sterilize the product were discolored, tarnished, and contained visible moisture. The air intake came from vents located about 100 feet from a mattress recycling facility that released copious amounts of dust and other contaminants into the air. The air vents in the "clean" rooms were covered with dirt and white fuzz. The metal shelf in the "clean" room used to prepare MPA was covered in a reddish-brown, cloudy substance.

56. Investigators determined that NECC's internal records showed dozens of instances of bacterial and fungal contamination within the NECC facility over at least the past nine months. NECC ignored these test results. NECC never even attempted to get rid of these microbial contaminants.

57. Eighty-three out of three-hundred twenty one observed vials from one of three recalled lots of MPA contained a greenish-black substance visible to the human eye. Seventeen other vials contained a white filamentous material. All fifty out of fifty vials tested confirmed the presence of live microbes (whether fungal or bacterial). The CDC and FDA later confirmed the presence of fungus in unopened vials of NECC's MPA. This is the same fungus that the CDC confirmed was present in at least forty fungal meningitis cases.

58. Inspections of NECC's sister company Ameridose revealed similarly deplorable conditions, including countless instances of visible contamination of the hoods and rooms used to prepare drug products, insect infestations, birds flying through areas where purportedly sterile products were packaged and stored, and tubs being used to collect rain water that poured through the chronically leaky roof above the "clean" rooms. Ameridose, like NECC, persistently ignored

and failed to investigate at least fifty-three instances of known microbiological contamination. Ameridose also hid adverse events associated with its products, failing to report them to the FDA as required by law and instead classifying these events as “patient responses” or “non-complaints” and taking no action to address them.

59. The CDC determined that three lots of 80 mg/ml MPA produced by NECC between May 21 and September 26, 2012 were contaminated with potentially deadly pathogens.

60. In late September 2012, NECC recalled the following lots of MPA (PF) 80 mg/ml that it had compounded and sold: MPA (PF) 80 mg/ml Injection, Lot #05212012@68, BUD 11/17/2012; MPA (PF) 80 mg/ml Injection, Lot #06292012@26, BUD 12/26/2012; and MPA (PF) 80 mg/ml Injection, Lot #08102012@51, BUD 2/6/2013.

61. NECC identified Specialty Surgery as one of the healthcare providers that received vials of MPA that were part of the September 2012 recall.

62. On or about October 3, 2012, the Massachusetts Department of Public Health (“DPH”) secured the surrender of NECC’s license to operate as a compounding pharmacy.

63. On October 6, 2012, NECC announced that it was recalling “all products currently in circulation that were compounded at and distributed from its facility in Framingham, Massachusetts.”

64. On or about October 8, 2012, at the request of DPH, Barry Cadden and Glenn Chin “voluntarily” ceased their practice as pharmacists. Lisa Cadden also has “voluntarily” ceased her practice as a pharmacist. Upon information and belief, none of them have practiced as a pharmacist since “voluntarily” ceasing their practice.

65. On or about October 22, 2012, the Massachusetts Board of Registration in Pharmacy authorized DPH to request the “voluntary” permanent surrender of the licenses of

Barry Cadden, Glenn Chin, Lisa Cadden and NECC. According to DPH, “[i]f the three pharmacists and NECC do not comply, the Board authorized staff to proceed with permanent revocation.”

66. One of the Massachusetts regulations promulgated by the Massachusetts Board of Registration in Pharmacy pertinent to NECC’s operation as a compounding pharmacy mandated that “[t]he premises of the pharmacy or pharmacy department shall at all times be kept in a clean and sanitary manner.” 247 CMR 6.02(1).

67. Over the last ten years, ARL has conducted sterility testing on samples of MPA compounded by NECC, including samples from Lot #05212012@68, BUD 11/17/2012; Lot #06292012@26, BUD 12/26/2012; and Lot #08102012@51, BUD 2/6/2013.

68. From May through August 2012, NECC sent several samples of its MPA to ARL for sterility testing. As one example, on or about May 21, 2012, NECC sent to ARL two 5ml vials of MPA from a batch of 6,528 vials that came from Lot 05212012@68, which had been compounded by NECC on May 21, 2012.

69. On May 22, 2012, ARL received and tested the two 5ml vials of MPA that NECC sent to ARL on or about May 21, 2012. ARL sent to NECC a Microbiology Report dated May 25, 2012, which stated that the two vials had been tested on May 22, 2012 and that the “preliminary” results from the sterility test using test method USP 71 showed that the two 5ml vials of MPA that NECC sent to ARL on or about May 21, 2012, were “sterile.” ARL’s report to NECC further noted that the preliminary results were observed “after approximately 72 hours of incubation.”

70. Pursuant to the protocols of test method USP 71, sterility testing on a batch of more than 6,000 vials of MPA should have been conducted on at least 20 vials from the batch.



71. On or about August 10, 2012, NECC caused one 5ml vial of MPA to be sent to ARL for sterility testing from a batch of several thousand vials that are from Lot #08102012@51, BUD 2/6/2013.

72. The Microbiology Reports issued by ARL to NECC between May and September 2012 concerning the sterility testing of MPA indicated that the sterility tests performed by ARL were conducted in compliance with USP 71.

73. During the summer of 2012, MSM and/or MSMSW sales representatives, on behalf of NECC and Ameridose, distributed copies of the May 25, 2012, ARL Microbiology Report concerning the testing of the vials of MPA from Lot 05212012@68 to customers and/or potential customers in a packet of marketing materials intended to highlight the safety and sterility of the MPA compounded by NECC.

74. ARL was aware of the risks posed by compounding pharmacies, specifically including the risks posed by NECC's compounding practices.

75. In 2002, ARL found that four samples of a steroid compounded by NECC were contaminated with potentially deadly endotoxins.

76. ARL allowed compounding pharmacies such as NECC to submit an inadequate number of samples for sterility testing, which practice did not comply with USP 71 requirements.

77. GDC which is an acronym for "Gregory D. Conigliaro" owns the real property and is responsible for maintenance and structural improvements at 685-705 Waverly Street, Framingham, Massachusetts.

78. From 1998 until at least October 2012, GDC leased a portion of the premises at Waverly Street to NECC, MSM and MSMSW.

79. In an on-line posting for a property management position at GDC, which appeared on or before October 25, 2012, GDC stated that it “owns an 88,000 square foot facility on seven acres in downtown Framingham. GDC currently has eight major tenants.” GDC described one of the duties and responsibilities of the GDC property manager as follows: “Insure all tenants operate their businesses in accordance with facility, local [and] state . . . rules and regulations.”

80. GDC maintained a high degree of control over the premises leased by NECC.

81. Until October 2012, NECC, Ameridose, ARL, Barry Cadden, Lisa Cadden, and Glenn Chin compounded, tested, marketed and/or distributed MPA.

82. GDC and Gregory Conigliaro knew that NECC was compounding preservative-free MPA at 697 Waverly Street, and further knew that this medication was injected into humans and was required to be sterile.

#### NECC and the Risks of Pharmacy Compounding

83. The serious risks of pharmacy compounding were also the subject of considerable public discussion in the pharmacy community and the medical community before the subject fungal meningitis outbreak. The risks associated with compounded drugs have been known for years.

84. In 2002, the CDC published a report regarding at least two cases of fungal meningitis arising from contaminated medication used in epidural injections. The report concluded that “purchasers of pharmaceuticals should determine if supplies are provided from a compounding pharmacy that...follows appropriate measures to ensure that injectable products are free of contamination.”



85. On March 24, 2005, *USA Today* published a front page article with the following headline: “**Safety concerns grow over pharmacy-mixed drugs**”. That article discussed growing concern over the fact that drugs produced in bulk by compounding pharmacies are not FDA approved and are not subject to the same oversight as drugs produced by pharmaceutical companies.

86. In 2006, the FDA conducted a survey of compounded drug products. They collected thirty-six samples from compounding pharmacies across the United States during unannounced visits. Twelve of the 36 samples (33%) failed analytical testing. The FDA survey concluded “poor quality compounded drugs are a serious public health concern, as improperly compounded products have been linked to grave adverse events, including deaths.”

87. In May 2007, the FDA published an article titled “The Special Risks of Pharmacy Compounding.” That article highlighted numerous adverse events involving compounded products. It also warned of the emergence of large scale compounding operations that were clearly operating outside the bounds of traditional compounding practice.

88. In 2010, the FDA posted an educational video on YouTube regarding concerns over the quality of compounded drugs.

89. On November 5, 2010, the American Society of Anesthesiologists, the American Society of Health-System Pharmacists (“ASHP”) and other medical societies published a joint report regarding drug shortages. That report included an article written by the ASHP stating as follows:

Compounding pharmacies have also pursued the production of drugs that are in short supply. Caution is warranted because preparations from these pharmacies may not meet applicable state or federal standards (e.g., United States Pharmacopeia chapter 797 or FDA labeling requirements). The sources of raw materials used by compounding pharmacies have been questioned, and apparent lapses in quality control have resulted in serious patient injury, including death.

Compounding pharmacies may also present patient risks; several deaths have been associated with improperly sterilized compounded products.

90. In May 2012, the CDC published a report regarding fungal infections arising from medications obtained from a compounding pharmacy. That report advised that “contamination of compounded sterile preparations has caused outbreaks. Since 1990, FDA has learned of approximately 200 adverse events associated with 71 compounded products.”

#### The Fungal Meningitis Outbreak

91. In September 2012, health officials identified an outbreak of fungal meningitis. Investigators traced the outbreak to MPA compounded by NECC.

92. According to the CDC, fungal meningitis occurs when the protective membranes covering the brain and spinal cord are infected with a fungus. Fungal meningitis is rare and usually caused by the spread of a fungus through blood to the spinal cord. Fungal meningitis is not transmitted from person to person.

93. According to the CDC, symptoms of meningitis include the following: new or worsening headache; fever; sensitivity to light; stiff neck; new weakness or numbness in any part of the body; slurred speech; and increased pain, redness or swelling at the injection site. Death may result from meningitis.

94. According to the CDC, symptoms of fungal meningitis are similar to symptoms of other forms of meningitis; however, they often appear more gradually and can be very mild at first. In addition to typical meningitis symptoms, like headache, fever, nausea, and stiffness of the neck, people with fungal meningitis may also experience confusion, dizziness, and discomfort from bright lights. Patients might just have one or two of these symptoms.

Ms. Norris is injected with MPA from NECC and suffers personal injury

95. On July 18 and September 25, 2012, Ms. Norris was injected by Dr. Kenneth Lister (“Dr. Lister”) at the Specialty Surgery Center with MPA.

96. Ms. Norris’ July 18 and September 25, 2012 injections came from one or more contaminated lots of MPA purchased from NECC. The contaminated lots were subsequently recalled by NECC.

97. Ms. Norris’ July 18 and/or September 25, 2012 injections of MPA caused her personal injury.

98. On or about September 28, 2012, Ms. Norris saw Dr. Rowan, chiropractor, for severe neck pain.

99. On October 2, 2012, Specialty Surgery directed Ms. Norris to the emergency room of the Cumberland Medical Center in Crossville, Tennessee where she was told that she was not within the affected dates of injection, meningitis was not a real concern for her, and she should just go home.

100. Ms. Norris did not discover, and reasonably could not have discovered, until after September 20, 2012 that she had received contaminated MPA.

101. On October 4, 2012, Ms. Norris received a call from Dr. Lister directing her to the Cumberland Medical Center for a spinal tap due to symptoms of fungal meningitis—headaches, neckache, and nausea.

102. By letter dated October 6, 2012, Ms. Norris was notified by Specialty Surgery that the MPA used in three (3) clinics across the State of Tennessee “may not have been sterile.”



103. On October 11, 2012, Ms. Norris began experiencing a new symptom of fungal meningitis—extreme sensitivity to light. After reporting this new symptom, Ms. Norris received a call from the State of Tennessee urging her to present for another spinal tap.

104. On October 12, 2012, Ms. Norris dutifully followed up with her primary care physician, Dr. Kimberly Peaslee (“Dr. Peaslee”) who sent her for another spinal tap at the Cookeville Regional Medical Center.

105. On October 14, 2012, Ms. Norris was informed by the Cumberland Medical Center that it had received a positive fungus result from the Mayo Clinic. Ms. Norris picked up the test results and was taken to and admitted to Cookeville Regional Medical Center as a positive case of fungal meningitis.

106. On October 16, 2012, Ms. Norris was discharged from Cookeville Regional Medical Center on a course of Viconazole which caused her constant sleepiness, loss of appetite, hallucinations, double vision, and confusion. She was removed from this medication by Dr. Mark Pierce on October 18, 2012.

107. On October 19, 2012, Ms. Norris was again urged by the State of Tennessee and Dr. Lister to undergo a third spinal tap. Ms. Norris consulted with Dr. Pierce who instructed her not to undergo a third spinal tap.

108. To this day, Ms. Norris continues to suffer from fungal meningitis/abscess symptoms which have not resolved and some of which have worsened. Ms. Norris has suffered and continues to suffer harm, injury, and damages as a result of her exposure to one or more of the three recalled contaminated lots of MPA.

CAUSES OF ACTION

COUNT I  
NEGLIGENCE  
(Against NECC Related Defendants)

109. As the designer, tester, compounder, seller, marketer and/or distributor of consumer products, the NECC Related Defendants owed a duty to Ms. Norris to comply with existing standards of care, and to exercise due care, in providing a safe and quality product to Ms. Norris.

110. Specifically, but without limitation:

- a. Ameridose, MSM/MSMSW, GDC, Barry Cadden, Gregory Conigliaro, Lisa Cadden, Douglas Conigliaro, Carla Conigliaro and GlennChin owed Ms. Norris a duty to provide MPA that was safe and free of contamination.
- b. ARL owed Ms. Norris a duty to properly conduct tests to insure that the MPA was safe and free of contamination.
- c. NECC Related Defendants sold MPA in bulk to Specialty Surgery, but they were not authorized to compound and sell MPA in bulk, instead they were only allowed to fill individual prescriptions for individual patients written by appropriately licensed health care providers.

111. Defendants breached those duties, and were otherwise negligent in their design, compounding, sale, testing, marketing and distribution of the recalled steroid medication, which was administered to Ms. Norris. The Defendants failed to exercise due care in accordance with the standard of care and skill required of, and ordinarily exercised by, a designer, compounder, tester, seller, marketer and distributor of steroid medications, as licensed to do so by the Commonwealth of Massachusetts. The Defendants, by and through their supervisors, staff and agents engaged in designing, compounding, storing, testing, selling, marketing and distributing MPA in a negligent manner.

112. Defendants further breached those duties by failing to properly design, compound, test and distribute MPA so that it would not be contaminated with fungus; by failing to properly maintain its facilities where it compounded its medications in a clean, sanitary manner; by failing to oversee the security and quality control of its compounding and distribution facilities; by allowing contaminated and unsafe compounded medications to reach the stream of commerce for use by Ms. Norris; and by failing to hold the components of the recalled MPA.

113. Ameridose, MSM/MSMSW, GDC, ARL, Barry Cadden, Gregory Conigliaro, Lisa Cadden, Douglas Conigliaro, Carla Conigliaro and Glenn Chin breached the duties owed to Ms. Norris by failing to use reasonable care in designing, compounding, testing, marketing, distributing and/or selling MPA.

114. The negligence of Ameridose, MSM/MSMSW, GDC, ARL, Barry Cadden, Gregory Conigliaro, Lisa Cadden, Douglas Conigliaro, Carla Conigliaro and Glenn Chin was a proximate cause of Ms. Norris' injuries and damages.

COUNT II  
NEGLIGENCE PER SE  
(Against all NECC Related Defendants except ARL)

115. Ameridose, MSM/MSMSW, GDC, Barry Cadden, Gregory Conigliaro, Lisa Cadden, Douglas Conigliaro, Carla Conigliaro and Glenn Chin owed Ms. Norris a duty to maintain the premises of the pharmacy "in a clean and sanitary manner[.]" 247 CMR 6.02(1), and free from contamination.

116. Ameridose, MSM/MSMSW, GDC, Barry Cadden, Gregory Conigliaro, Lisa Cadden, Douglas Conigliaro, Carla Conigliaro and Glenn Chin breached the duties owed to Ms. Norris by failing to use reasonable care in maintaining the premises of the pharmacy "in a clean and sanitary manner[.]" 247 CMR 6.02(1), and free from contamination.



117. Defendants also violated Massachusetts' laws and its pharmacy licensing obligations.

118. The aforementioned actions by Ameridose, MSM/MSMSW, GDC, Barry Cadden, Gregory Conigliaro, Lisa Cadden, Douglas Conigliaro, Carla Conigliaro and Glenn Chin were a proximate cause of Ms. Norris' injuries and damages.

COUNT III  
NEGLIGENT SUPERVISION  
(Against NECC Related Defendants)

119. Defendants Ameridose, MSM/MSMSW, GDC, ARL, Barry Cadden, Gregory Conigliaro, Lisa Cadden, Douglas Conigliaro, Carla Conigliaro and Glenn Chin had an obligation and duty to exercise due care, and comply with the then existing standard of care, to investigate and hire professional and competent employees to create, test, package, market and distribute the compounded medications and to maintain the facility and its premises, and to make sure the compounded drugs did not create any harm or risk to Ms. Norris and others who received the compounded medication.

120. In breach of those duties, Defendants failed to exercise due care and failed to supervise their employee(s) or agent(s), who were at all times working within the scope of their employment and authority. Specifically, and without limitation:

- a. The Defendants failed to monitor and test the steroid medication and were otherwise negligent in supervision of their employees.
- b. Defendants also failed to monitor and supervise the testing of the compounded medications.
- c. The Defendants were negligent in hiring, training, and supervising their employees.

121. The Defendants knew, or should have known, that their employee(s) or agent(s) did not follow proper procedures and knew or should have known of the risks created by failing to do so.

122. As a direct and proximate cause of the breach of those duties, the Defendants permitted the steroid to become contaminated and distributed to patients including Ms. Norris.

123. The aforementioned actions by Ameridose, MSM/MSMSW, GDC, ARL, Barry Cadden, Gregory Conigliaro, Lisa Cadden, Douglas Conigliaro, Carla Conigliaro and Glenn Chin were a proximate cause of Ms. Norris' injuries and damages.

COUNT IV  
PUBLIC NUISANCE  
(Against Barry Cadden, Gregory Conigliaro and GDC)

124. At all relevant times, Barry Cadden, Gregory Conigliaro and/or GDC were in control of the property and improvements at 697 Waverly Street, Framingham, Massachusetts.

125. Barry Cadden, Gregory Conigliaro and GDC owed a duty to maintain the property and improvements at 697 Waverly Street, Framingham, Massachusetts in a condition that was free from contamination.

126. Barry Cadden, Gregory Conigliaro and GDC failed to exercise reasonable care in maintaining the property and improvements at 697 Waverly Street, Framingham, Massachusetts.

127. The failure by Barry Cadden, Gregory Conigliaro and GDC to maintain the property and improvements at 697 Waverly Street, Framingham, Massachusetts was a proximate cause of the multistate epidemic of fungal meningitis and infections caused by the contaminated MPA.

128. Barry Cadden, Gregory Conigliaro and GDC unreasonably and significantly interfered with the public health and the public safety.



129. Barry Cadden, Gregory Conigliaro and GDC unreasonably and significantly interfered with the public right expressed in 247 CMR 6.02(1).

130. The public nuisance created by Barry Cadden, Gregory Conigliaro and GDC was a proximate cause of Ms. Norris' injuries.

131. The public nuisance created by Barry Cadden, Gregory Conigliaro and GDC has caused Ms. Norris special injury in that she has sustained injuries to her personal health.

COUNT V  
PRODUCT LIABILITY CLAIMS  
(Against Specialty Surgery)

132. The MPA injected into Ms. Norris on July 18 and September 11, 2012 was compounded by NECC.

133. On December 21, 2012, NECC filed a voluntary petition pursuant to Chapter 11 of Title 11 of the United States Bankruptcy Code in the United States Bankruptcy Court for the District of Massachusetts, In re: New England Compounding Pharmacy, Inc., No. 12-19882-HJB.

134. Pursuant to 11 U.S.C. § 362(a)(1) certain actions against NECC are stayed following its bankruptcy petition.

135. Ms. Norris commenced an action seeking a judgment against NECC before December 21, 2012.

136. Ms. Norris' claims that arose before NECC's petition in bankruptcy are subject to the automatic stay provisions of 11 U.S.C. § 362(a)(1).

137. NECC has ceased operations.

138. NECC is unable to pay its debts as they fall due.

139. NECC is unable to pay its debts in the ordinary course of its business.

140. NECC's liabilities exceed its assets.

141. NECC is insolvent.

142. On July 24, 2013, the United States Bankruptcy Court for the District of Massachusetts in In re: New England Compounding Pharmacy, Inc., No. 12-19882-HJB, ordered that with respect to certain claims, including those asserted here, NECC is presently insolvent and has been insolvent at all times since the petition date.

143. Specialty Surgery procured the MPA injected into Ms. Norris from NECC.

144. NECC's product was defective and unreasonably dangerous when it left NECC's control because it was contaminated with lethal pathogens, and it was in substantially the same condition at the time that Specialty Surgery injected it into Ms. Norris on July 18 and September 25, 2012.

145. Specialty Surgery charged Ms. Norris for epidural steroid injections it administered to her.

146. Specialty Surgery acted as a seller or distributor of MPA compounded by NECC when it sold and administered epidural steroid injections to patients, including Ms. Norris.

147. Specialty Surgery was engaged in the business of selling MPA compounded by NECC.

148. Accordingly, Specialty Surgery is a "seller" as defined by Tenn. Code Ann. § 29-28-102(7).

149. Tenn. Code Ann. § 29-28-106(4) and/or (5) authorizes Ms. Norris to prosecute product liability claims against Specialty Surgery as the seller of the MPA injected into Ms. Norris because the compounder of the product, NECC, cannot be served with process in this state and/or has been or will be judicially declared insolvent.

150. The MPA that Specialty Surgery injected into Ms. Norris was unreasonably dangerous and defective at the time it left its control because it was contaminated with lethal pathogens.

151. Specifically, the MPA was in a defective condition and unreasonably dangerous at all relevant times because it was unsafe for normal or anticipated handling as defined by Tenn. Code Ann. § 29-28-102(2).

152. The MPA sold and distributed by Specialty Surgery was neither merchantable nor fit for the purpose for which it was produced and sold. Accordingly, Specialty Surgery breached its warranties, both express and implied, as stated in Tenn. Code Ann. §§ 47-2-313, 47-2-314 and 47-2-315, including its warranty of fitness for a particular purpose.

153. Specialty Surgery is strictly liable for the injuries and losses caused by the unreasonably dangerous and defective steroids injected into Ms. Norris.

#### DAMAGES

154. As a direct and proximate result of the Defendants' wrongful conduct as described above, Ms. Norris has suffered physical injuries, physical and mental pain and suffering, mental anguish, and loss of enjoyment of life.

155. The long term effects of Ms. Norris' condition are unknown.

156. Ms. Norris remains under the care of physicians. Ms. Norris has incurred and continues to incur medical and other expenses.

#### PUNITIVE DAMAGES

157. The above described acts and omissions on the part of the Defendants were reckless and intentional. Defendants were aware of, but consciously disregarded, a substantial and unjustifiable risk of such a nature that their disregard constitutes a gross deviation from the



standard of care that an ordinary person would exercise under all the circumstances. Ms. Norris therefore is entitled to an award of punitive damages against the Defendants.

CAPS FOUND IN TENN. CODE ANN. § 29-39-102 AND § 29-39-104  
ARE UNCONSTITUTIONAL AND VOID *AB INITIO*

158. On October 1, 2011, the Tennessee Civil Justice Act went into effect, enacting “caps” in all Tennessee personal injury cases for non-economic damages and punitive damages. Tenn. Code Ann. § 29-39-102; and Tenn. Code Ann. § 29-39-104. Under that Act, Ms. Norris’ non-economic damages are purportedly capped at \$750,000, and her ability to recover punitive damages is capped at twice the compensatory damages up to a maximum of \$500,000.

159. Tenn. Code Ann. § 29-39-102 and Tenn. Code Ann. § 29-39-104 are unconstitutional deprivations of Ms. Norris’ constitutionally protected right to trial by jury. Those provisions violate Article I, Section 6 of the Constitution of the State of Tennessee, which provides that the right of trial by jury shall remain inviolate. In addition, the subject statutory caps violate Article I, Section 17 of the Tennessee Constitution which states that all courts shall be open, and every man shall have a remedy for injury done by due course of law and without denial or delay. The subject statutory caps usurp the powers of the Judicial Branch in violation of Article II, Sections 1 & 2 of the Tennessee Constitution. In addition, the subject statutory caps violate Article XI, Section 16 of the Tennessee Constitution which indicates that the rights of citizens articulated in Tennessee’s Bill of Rights “shall never be violated on any pretense whatever . . . and shall forever remain inviolate.” Therefore, Ms. Norris requests a declaration, pursuant to Tenn. Code Ann. § 29-14-103, that the statutory caps are void *ab initio* and of no force and effect.

160. Pursuant to Tenn. Code Ann. § 29-14-107, a copy of this Complaint is being served on the Attorney General of the State of Tennessee, notifying the State of Tennessee

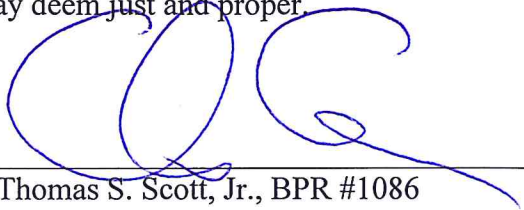
Attorney General that Ms. Norris is challenging the constitutionality of Tenn. Code Ann. § 29-39-102 and Tenn. Code Ann. § 29-39-104.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff, Jocelyn K. Norris, requests the following relief:

- A. A judgment for compensatory damages in excess of \$75,000;
- B. A judgment for punitive damages in an amount to be determined by the trier of fact;
- C. A jury to determine all disputed factual issues;
- D. For costs of this cause; and
- E. For such further relief as the Court may deem just and proper.

Respectfully submitted,



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*Attorneys for Plaintiffs James and Michelle Palmer*

**UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF MASSACHUSETTS**

**JOCELYN KAE NORRIS** : **CIVIL ACTION NO. 1:13-cv-12682-FDS**  
:  
**Plaintiff,** : **MDL No. 2419**  
:  
**v.** : **Master Docket No. 1:13-md-2419-FDS**  
:  
:  
**UNIFIRST CORPORATION, D/B/A** : **Honorable F. Dennis Saylor**  
:  
**UNICLEAN CLEANROOM** :  
:  
**SERVICES, and SPECIALTY** : **DEMAND FOR JURY TRIAL**  
:  
**SURGERY CENTER, PLLC D/B/A** :  
:  
**SPECIALTY SURGERY CENTER,** :  
:  
**Defendants.** :  
:

**SHORT FORM COMPLAINT  
AGAINST UNAFFILIATED DEFENDANTS**

Plaintiff Jocelyn Kae Norris, complaining against Defendants, alleges as follows:

**FIRST COUNT**

1. Pursuant to MDL Order No. 7, entered in In Re: New England Compounding Pharmacy, Inc. Products Liability Litigation, Master Docket No. 1:13-md-2419-FDS, the undersigned counsel hereby submit this Short Form Complaint and Jury Demand against Defendants, and adopt and incorporate by reference the allegations in Plaintiffs' Master Complaint, with attachments, and any and all amendments thereto.

2. Plaintiff Jocelyn Kae Norris is a resident of the State of Tennessee.

3. Plaintiff Jocelyn Kae Norris brings this action:

☒ On behalf of herself.

☐ As the representative of \_\_\_\_\_, who is a living person.

☐ As the Administrator, Administrator ad Prosequendum, or other representative of the Estate of \_\_\_\_\_ (hereinafter "Decedent"), who died on \_\_\_\_\_.

4. **Intentionally Omitted.**

5. Plaintiff asserts she was administered New England Compounding Pharmacy, Inc. ("NECC") drug methylprednisolone acetate (hereinafter referred to as "NECC drug"), causing injuries and damages.

6. The aforesaid administration of the NECC drug occurred on July 18 and September 25, 2012, by Kenneth Lister, M.D. at Defendant Specialty Surgery Center, PLLC d/b/a Specialty Surgery Center ("Clinic Related Defendant"), located in Crossville, Tennessee.

7. **Intentionally Omitted.**

8. Plaintiff adopts and incorporates by reference the following Causes of Action asserted against Defendants in the Master Complaint:

☒ COUNT II: NEGLIGENCE AND GROSS NEGLIGENCE (Against UniFirst)

☒ COUNT III: NEGLIGENCE AND GROSS NEGLIGENCE (Against Clinic Related Defendant)

☐ COUNT IV: VIOLATION OF CONSUMER PROTECTION STATUTES (Against Clinic Related Defendants)

Plaintiff(s) allege violation of the following consumer protection statute(s): [List statutes. Note that N.J.S.A. 56:8-1 *et seq.* was inadvertently omitted from the Master Complaint]

☐ COUNT VI: VIOLATION OF M.G.L. C. 93A (Against UniFirst)

☐ COUNT VII: BATTERY (Against Clinic Related Defendants)

☒ COUNT VIII: FAILURE TO WARN (Against Clinic Related Defendant)

- ☒ COUNT IX: TENNESSEE PRODUCT LIABILITY CLAIMS (Against Clinic Related Defendant)
- ☐ COUNT X: AGENCY (Against Clinic Related Defendants)
- ☐ COUNT XI: CIVIL CONSPIRACY (Against Clinic Related Defendants)
- ☐ COUNT XII: WRONGFUL DEATH PUNITIVE DAMAGES (Against UniFirst and Clinic Related Defendants)
- ☒ COUNT XIII: LOSS OF CONSORTIUM (Against UniFirst and Clinic Related Defendant)
- ☒ COUNT XIV: PUNITIVE DAMAGES (Against UniFirst and Clinic Related Defendant)

9. **Intentionally Omitted.**

10. On or about July 17, 2013, Plaintiff gave pre-suit notice of her potential medical malpractice claim to Clinic Related Defendant and, in doing so, extended Tennessee's one (1) year medical malpractice statute of limitations by 120 days to at least January 23, 2014. Accordingly, Plaintiff expressly reserves her rights to amend her Complaint to add allegations of medical malpractice under and in conformity with Tennessee's medical malpractice act, Tenn. Code Ann. § 29-26-101, et seq. On or about December 18, 2013, Plaintiff sent or served pre-suit notice or demand requirements necessary under M.G.L.C. 93A to bring a claim for violation of M.G.L.C. 93A (as set forth in Count VI of the Master Complaint) and will seek leave to assert such claim promptly after the time period for giving notice has expired.

11. Plaintiff Jocelyn Kae Norris has suffered and continues to suffer physical injuries (including multiple spinal taps, headaches, neck pain and stiffness, high fever, nausea, extreme vision/light sensitivity, extreme back pain, loss of memory, macular degeneration, ineffective pain management, and mild dementia symptoms), physical and mental pain and suffering, mental anguish, loss of enjoyment of life, loss of earning capacity, and loss of opportunity to be treated



for back pain management with steroidal injections as a result of the Defendants' negligent misconduct, acts, and omissions.

12. Plaintiff Jocelyn Kae Norris suffered and continues to suffer the following damages as a result of the administration of NECC's drug(s): severe pain and suffering, mental anguish, disability, emotional distress, past and future medical care and treatment, increased living and support expenses, loss of enjoyment of life, and medical expenses, both past and future.

13. **Intentionally Omitted.**

Plaintiff reserves the right to amend this Complaint to add allegations and claims against individuals or entities currently omitted (in light of the Court's order permitting a Master Complaint naming defendants affiliated with NECC and currently participating in mediation by December 20) and to add or amend allegations against Defendants named herein based, in part, on further discovery.

WHEREFORE, Plaintiffs demands Judgment against Defendants awarding compensatory damages, punitive damages, attorneys' fees, interest, costs of suit, and such further relief as the Court deems equitable and just. Pursuant to Tenn. Code Ann. § 29-28-107, Plaintiff prays for damages in an amount not to exceed \$3,000,000.00.

**SECOND COUNT**

14. Plaintiff re-alleges and incorporates by reference each of the foregoing paragraphs as if set forth at length herein.

15. Plaintiffs incorporate all allegations and counts contained in Plaintiffs' Original Complaint found at Docket No. 1, in the litigation styled Jocelyn Kae Norris v. Ameridose LLC, et al.; United States District Court, District of Massachusetts, 1:13-cv-12682, (MDL No. 1:13-md-2419-FDS) together with all prayers for relief stated therein.

16. Plaintiff Jocelyn Kae Norris has suffered and continues to suffer injuries as set forth in Paragraph 11 herein.

17. Plaintiff Jocelyn Kae Norris has suffered and continues to suffer damages as set forth in Paragraph 12 herein.

18. **Intentionally Omitted.**

WHEREFORE, Plaintiff demands Judgment against Defendants awarding compensatory damages, punitive damages, attorneys' fees, interest, costs of suit, and such further relief as the Court deems equitable and just.

### **JURY DEMAND**

Plaintiff hereby demands a trial by jury.

Respectfully submitted, this 19<sup>th</sup> day of December, 2013.

/s/ Christopher T. Cain  
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### **CERTIFICATE OF SERVICE**

I hereby certify that on December 19, 2013, a true and exact copy of the foregoing was filed electronically. Notice of this filing will be sent by operation of the Court's electronic filing system to all parties indicated on the electronic filing receipt. Parties may access this filing through the Court's electronic filing system.

/s/ Christopher T. Cain